UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WALGREEN CO. and KROGER SPECIALTY PHARMACY, INC., Plaintiffs, v. CELGENE CORPORATION; BRISTOL-MYERS SQUIBB COMPANY; NATCO PHARMA LIMITED; and TEVA PHARMACEUTICALS USA, INC., Defendants.	Case No. **COMPLAINT** JURY TRIAL DEMANDED

Plaintiffs Walgreen Co. ("Walgreen") and Kroger Specialty Pharmacy, Inc. ("KSP") sue Defendants Celgene Corporation ("Celgene"), Bristol-Myers Squibb Company ("BMS"), Natco Pharma Limited ("Natco") and Teva Pharmaceuticals USA, Inc. ("Teva") under the antitrust laws of the United States. For their Complaint, Walgreen and KSP allege as follows:

I. NATURE OF THE CASE

1. This is a civil antitrust action challenging a multifaceted, anticompetitive scheme initiated by Defendants Celgene and BMS and later joined by Defendants Natco and Teva that has delayed generic competition to Celgene's and BMS's $8.7 *billion*-dollar-a-year drug Revlimid since at least 2019 and will continue to result in artificially high generic prices, and artificially low generic substitution, until at least January 30, 2026. As part of this anticompetitive scheme, Celgene and BMS: (1) manipulated the safety program designed to protect patients from lenalidomide's teratogenic properties and refused to sell samples to would-be generic competitors; (2) prevented ingredient suppliers from supplying active pharmaceutical ingredient ("API") to would-be generic competitors; (3) fraudulently obtained various patents

from the U.S. Patent and Trademark Office ("USPTO") for Revlimid and their associated safety distribution protocols; (4) filed baseless citizen petitions with FDA to stymie generic approvals; (5) commenced serial patent infringement lawsuits without regard to their merit or likely outcome; and (6) resolved certain of those lawsuits by entering into anticompetitive reverse payment agreements with their generic competitors that delayed the entry of generic lenalidomide, allocated the lenalidomide market among the parties to those agreements, and delayed normal generic competition until at least January 21, 2026.

2. When Natco and its marketing partners were able to prosecute and ultimately obtain approval of an Abbreviated New Drug Application ("ANDA") for a generic version of Revlimid despite Celgene and BMS's best efforts to prevent it, all four Defendants joined forces to suppress and further delay generic competition by executing an anticompetitive reverse payment settlement agreement. In return for Natco's agreement not to launch any generic version of Revlimid until March 2022 and then to refrain from fully supplying the market with generic Revlimid until January 2026, the agreement guaranteed Natco a limited share of the generic Revlimid market beginning in 2022 that gradually increases through January 2026. Pursuant to that agreement, Teva launched Natco's approved generic product in 2022, but limited its sales of generic Revlimid to 7% of the total Revlimid market, as opposed to the 90% share that an AB-rated generic normally would be expected to achieve. As a result of that agreement, Walgreen, KSP and other purchasers were deprived of any generic version of Revlimid from at least 2019 through March 2022; have been forced to pay artificially high generic prices and face limited supplies of generic Revlimid beginning in March 2022; and will be deprived of the normal and expected results of generic competition in the Revlimid market until at least January 2026.

3. The unlawful reverse payment to Natco and its marketing partner Teva included: (1) a volume limited, royalty-free license guaranteeing Natco and Teva a limited share of the Revlimid market at prices close to the price of branded Revlimid, worth hundreds of millions of dollars to Natco and Teva; and (2) most-favored entry clauses ("MFE clauses") that both deterred later-filing generics from challenging Celgene's patents and induced Natco to accept a later entry date. These MFE clauses laid the foundation for a series of similar output-restriction and market-allocation agreements with later-filing generics. Celgene settled these later suits on terms that were consistent with the initial Natco settlement and ensured high generic prices and limited generic supplies of Revlimid until at least January 31, 2026.

4. In 1998, Celgene obtained FDA approval to market Thalomid® (thalidomide) for a complication of leprosy known as erythema nodosum leprosum ("ENL"). In 2005, Celgene successfully developed a thalidomide analogue, Revlimid® (lenalidomide), and obtained FDA approval to market it for a specific chromosomal variant of myelodysplastic syndromes ("MDS"), a form of cancer. Celgene would go on to obtain FDA approvals for the use of Revlimid to treat other forms of cancer, including a subset of multiple myeloma ("MM") patients in 2006, and later for a subset of mantle cell lymphoma ("MCL") patients in 2013.

5. Thalidomide, the active ingredient of Thalomid and precursor to the active ingredient of Revlimid, dates back to the 1950's and 1960's, when it was banned for decades because it caused severe birth defects in babies born to women taking it to treat pregnancy-related morning sickness. Despite the invention of thalidomide decades ago, Celgene and BMS have successfully schemed and conspired to insulate Revlimid from generic competition,

allowing it to maintain its monopoly on the drug and prevent generic competition since at least 2019.[1]

6. In fact, Celgene has routinely increased its price either once or twice per year. A 2020 congressional report examining Celgene's pricing practices observed that "[s]ince launching Revlimid in 2005, Celgene raised the price of the drug 22 times, from $215 per pill to $719 per pill. After Bristol-Myers Squibb obtained the rights to Revlimid [in] November [2019], it raised the price of Revlimid again, to $763 per pill."[2] As Celgene's former Senior Vice President of Sales and Marketing testified, Celgene's executives could raise the price of Revlimid "any time they wanted."[3]

7. In 2006, a month's supply of Revlimid cost $6,195. In 2010, the price was about $8,000 for a one-month supply. Due to these price increases, a monthly course of Revlimid as of late 2020 cost $16,023—more than triple the price since its launch.[4]

8. In spite of these price increases, Celgene never saw a decrease in the quantity demanded for Revlimid because the only close economic substitute to Revlimid is an AB-rated generic version of Revlimid that could be substituted for the drug by pharmacists, and Defendants ensured that no such generic product was available until March 2022.

9. Celgene's monopolistic efforts with respect to Revlimid have been enormously profitable. Since 2014, Celgene has sold nearly $47 billion worth of Revlimid in the U.S.:

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[1] *See* U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigation*: *Celgene and Bristol-Myers Squibb—Revlimid* (Sept. 30, 2020), at p. 17, *available at* oversight.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf (accessed Oct. 12, 2022) ("Oversight Committee Revlimid Report") ("Celgene uses a series of anticompetitive tactics to suppress generic competition and maintain its high price of Revlimid.")

[2] *Id.*, at p.i.

[3] *Id.*, at p.4.

[4] *Id.* at p.i.

Revlimid

Year	Approximate U.S. Sales
2014	$ 2.9 billion
2015	$ 3.5 billion
2016	$ 4.4 billion
2017	$ 5.4 billion
2018	$ 6.5 billion
2019	$ 7.2 billion
2020	$ 8.3 billion
2021	$ 8.7 billion

10. After Celgene executed an anticompetitive reverse payment agreement with first filer Natco and its marketing partners in December 2015, Celgene's consistent and egregious price hikes exploded Revlimid's monopoly profits. U.S. revenue skyrocketed from $3.5 billion in 2016 to $8.7 billion in 2021 – the last year before (delayed but limited) generic entry. Revlimid is one of the ten highest-grossing drugs worldwide.

11. Defendants' anticompetitive tactics to block and delay generic entry have caused Plaintiffs to pay overcharges on their purchases of Revlimid and generic Revlimid. Plaintiffs bring this action seeking treble damages and permanent injunctive relief.

II. JURISDICTION AND VENUE

12. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, seeking treble damages, permanent injunctive relief and other relief for Defendants' violations of the Sherman Act. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337.

13. This Court has personal jurisdiction over Defendants because Defendants are present in the United States, do business in the United States, have registered agents in the United States, may be found in the United States, and are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

14. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c) because Defendants are found and transact business in this district.

III. PARTIES

15. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates pharmacies at which it dispenses prescription drugs, including Revlimid, to the public. Walgreen purchased substantial quantities of Revlimid directly from Defendants Celgene and BMS during the relevant period, and has purchased generic Revlimid directly from Teva since March 2022. Walgreen brings this action in its own behalf and as the assignee of Walgreens Specialty Pharmacy, LLC d/b/a Alliance Rx Walgreens Pharmacy, an indirect wholly owned subsidiary of Walgreens Boots Alliance, Inc., Walgreen's parent corporation.

16. Walgreens Specialty Pharmacy, LLC d/b/a Alliance Rx Walgreens Pharmacy ("Alliance Rx") is a Delaware limited liability company having its principal place of business at 7003 President's Drive, Orlando, Florida 32809. Alliance Rx owns and operates specialty pharmacies at which it dispenses prescription drugs, including Revlimid, to the public. Alliance Rx purchased substantial quantities of Revlimid directly from Defendants Celgene and BMS during the relevant period, and has purchased generic Revlimid directly from Teva since March 2022. Alliance Rx is an indirect wholly owned subsidiary of Walgreens Boots Alliance, Inc.,

Walgreen's parent corporation, and has expressly assigned its claims against Defendants in this action to Walgreen.

17. Plaintiff Kroger Specialty Pharmacy, Inc. ("KSP") is a Florida corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. KSP owns and operates specialty pharmacies in several states at which it dispenses prescription drugs, including Revlimid, to the public. KSP purchased substantial quantities of Revlimid directly from Defendants Celgene and BMS during the relevant period, and has purchased generic Revlimid directly from Teva since March 2022.

18. Defendant Celgene Corporation is a drug manufacturer incorporated in Delaware and headquartered at 86 Morris Avenue, Summit, New Jersey. Celgene manufactures and markets Revlimid. Celgene was acquired by BMS in 2019.

19. Defendant Bristol-Myers Squibb Company is a drug manufacturer incorporated in Delaware and headquartered at 430 E. 29th Street, New York, NY 10016.

20. Celgene Corporation is a wholly owned subsidiary of BMS. BMS completed the acquisition of Celgene in November 2019 after the companies had executed a merger agreement in January 2019. "The companies' public statements and filings with the Securities and Exchange Commission make clear that Revlimid, which had nearly $10 billion in annual revenue, was a key asset in the transaction. [¶] The companies' joint SEC filings for the merger acknowledge that Revlimid revenue was so critical that any expiration of its patent protection sooner than anticipated 'would be harmful to the combined company and could have a material adverse effect on its business, financial condition or results of operations.'"[5]

[5] Oversight Committee Revlimid Report, at p. 2 (footnote omitted).

21. Defendant Natco Pharma Limited is an Indian drug manufacturer headquartered at Natco House, Road No. 2, Banjara Hills, Hyderabad-500, 034, India. Natco develops and markets drugs throughout the world, including in the United States. In September 2010, Natco filed the first Abbreviated New Drug Application ("ANDA") for generic Revlimid in 5 mg, 10 mg, 15 mg and 25 mg strengths. In December 2010, Natco announced a marketing and development agreement for generic Revlimid with a marketing partner, Watson Pharmaceuticals, Inc. ("Watson"), and Watson's subsidiary, Arrow International Limited ("Arrow").

22. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva acquired Watson and Watson's subsidiary Arrow, Natco's marketing partners for generic Revlimid, and launched Natco's generic Revlimid product in March 2022, pursuant to the terms of the unlawful reverse-payment, output-restriction and market-allocation agreement described in detail below.

IV. REGULATORY BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

23. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person both pays for and chooses the product, the price of the product plays a role in the person's choice of products and, consequently, manufacturers have an appropriate incentive to lower the prices of their products.

24. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from

dispensing many pharmaceutical products, including Revlimid, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) is obligated to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

25. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

26. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. Reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

27. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning

the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

28. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If any such patents issue after the FDA approves the NDA, the manufacturer must subsequently list them in the Orange Book within thirty days of their issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

29. The FDA relies completely on the brand manufacturer's representations about patent validity and applicability, as it does not have the resources or authority to verify the validity or applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

30. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. It must only show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and

to the same extent as the brand drug. In other words, the ANDA must demonstrate that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

31. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

32. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic products, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

33. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had increased many-fold to $300 billion.

D. Paragraph IV Certifications

34. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

35. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

36. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When only one generic is on the market, the generic price, while lower than the branded price, is much higher than the price once multiple generic

sellers enter the market. Generics are usually at least 20% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generics on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

37. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity. This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

E. Benefits of Generic Drugs

38. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 80% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as Plaintiffs, a generic typically achieves at least a 70% substitution rate within 90 days. As a result, brand name companies such as Celgene and BMS view competition from generic drugs as a grave threat to their bottom lines.

39. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists liberally and substantially substitute the generic version when presented with a prescription for its brand-name equivalent. Since passage of the Hatch-Waxman Amendments,

every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for brand prescriptions unless the prescribing physician has specifically countermanded that substitution by writing "dispense as written" or equivalent language on the prescription.

40. There is an incentive to choose the less expensive generic equivalent at every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices of generic products.

41. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the reverse-payment agreements at issue here.

F. The Impact of Authorized Generics

42. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period pursuant to its own approved NDA. Such an "authorized generic" or AG is literally identical to the brand drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition from an AG during the 180-day exclusivity period substantially reduces the price of both the ANDA filer's generic drug and the authorized generic and, in addition, forces the first-filer to share the generic

sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

43. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the revenues generated by the first-filer's generic product by approximately 50% during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

44. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

45. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their brand drugs in response to the entry of AB-rated generics. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the brand drug at the same rate at which it was raised prior to generic entry.

46. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such agreements

compensate the generic for delaying entry of its generic drug by eliminating competition between the ANDA filer's generic and the authorized generic, giving the ANDA filer a monopoly on generic sales.

G. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

47. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand name manufacturer sues the potential generic competitor for alleged patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

48. In connection with the resolution of patent litigation arising out of Paragraph IV certifications, some brand name manufacturers have entered into settlements in which the brand name manufacturer pays off its generic competitors in exchange for a delay in generic competition. These exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or "reverse-payment agreements." Brand and generic manufacturers execute exclusion payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers. The brand name manufacturer preserves increased profits by keeping its monopoly intact via a payment of some of the monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product. The Supreme Court held that such agreements are subject to antitrust scrutiny and potentially condemnation under the rule of reason in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

49. Initially, reverse-payment agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and lawsuits, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. Because the profits to be gained by delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

H. FDA Mandated REMS Programs

23. Since at least the 1960's, FDA has examined and implemented various methods for managing risks related to pharmaceutical products, including disclosure (warnings) and labelling requirements. The Controlled Substances Act of 1970 saw the regulation of manufacturers, prescribers, dispensers, and labels, and permitted FDA to require warnings on packages.[6]

24. In the 1990s, FDA began to work with manufacturers to develop risk management programs for drugs with dangerous side effects. Then, in the 2000's, FDA established Risk Minimization Action Plans ("RiskMAPs"), whereby manufacturers voluntarily instituted risk minimizing plans.

25. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which codified the Risk Evaluation and Mitigation Strategies ("REMS") to be implemented with respect to certain pharmaceutical products "that have already been approved" and directed the Secretary of Health and Human Services ("HHS") to establish an active post-market drug surveillance infrastructure.[7]

[6] 21 U.S.C. § 801, *et seq.* (2002).

[7] 21 U.S.C. § 355-1(f)(8).

26. A REMS can include, *inter alia*, a medication guide, patient package inserts, and/or restrictions on the distribution of the drug.

27. Since their enactment in 2007, REMS have been increasingly common in FDA's approval process. Roughly 40% of new drugs have REMS programs.

28. REMS are intended to give FDA authority to condition drug approval on the implementation of a program designed to address serious risks associated with particular pharmaceutical products. The intention is not to make drugs, or drug samples, less available for appropriate use. In fact, §505-1(f)(8) of the FDAAA explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. The FDAAA does not prohibit the sale of REMS-subject drugs to generic manufacturers that will use those drugs in controlled bioequivalence ("BE") testing, nor does it give an NDA holder the right to interfere with a competitors' ability to purchase necessary drug samples.

29. REMS abuse is anticompetitive behavior that unlawfully excludes market entry by generic competitors, costing the U.S. healthcare system more than $5 billion annually.[8] In 2016, Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research ("CDER"), testified that brand companies often use REMS programs "as an excuse to not give the drug to the generics so they can compare it to their drug." This behavior, she noted, causes "barriers and delays in getting generics on the market."[9]

30. On December 20, 2019, Congress enacted material portions of the "Creating and Restoring Equal Access to Equivalent Samples Act of 2016" (commonly known as

[8] Association for Accessible Medicines, *Increase Competition & Access – Support CREATES Act*, https://accessiblemeds.org/campaign/increase-competition-and-access-rems (last visited Oct. 13, 2022).

[9] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

"CREATES") to combat REMS abuse.[10] CREATES establishes a standalone private right of action for qualifying developers of generic drugs to sue branded drug manufacturers that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms."[11] Available remedies include immediate provision of sufficient quantities of samples of the drug on commercially reasonable terms, attorneys' fees and costs, and civil fines "sufficient to deter" a defendant brand manufacturer from withholding samples to other companies developing generics in the future.[12]

31. CREATES establishes a prospective counterbalance to monopolistic schemes by brand manufacturers who abuse the REMS process to unlawfully monopolize the market for a drug by excluding generic competition beyond the period and scope afforded by a lawfully obtained patent, but it does not provide a remedy for past REMS abuse.[13]

I. Citizen Petitions

32. Section 505(j) of the FDCA creates a mechanism that allows a person to file a petition with FDA requesting that the agency take, or refrain from taking, any form of administrative action. Known as a "citizen petition," this regulatory mechanism has also been used by brand manufacturers to delay generics unlawfully.

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[10] Material portions of CREATES were incorporated into the Further Consolidated Appropriations Act, 2020, Pub. L. 116-94.

[11] 21 U.S.C. § 355-2(b)(1).

[12] 21 U.S.C. § 355-2(b)(4).

[13] Senator Patrick Leahy's (D-VT) committee comments echo the misconduct alleged against Celgene here: "The first delay tactic addressed by the CREATES Act involves withholding of drug samples that generic manufacturers need to gain regulatory approval. Federal law requires generic competitors to prove that their low-cost alternative is equally safe and effective as the brand-name drug with which they wish to compete. Unfortunately, some brand-name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition." Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Statement of Senator Patrick Leahy (June 21, 2016), https://www.judiciary.senate.gov/download/06-21-16-leahy-statement-2.

33. A citizen petition allows a citizen to notify FDA of its genuine concerns about safety, scientific or legal issues regarding a product at any time before or after it enters the market.

34. Pursuant to FDA regulations, FDA must respond to a citizen petition within 180 days of receipt with a grant in whole or in part, or a denial of the petition. FDA can provide a tentative response with an estimate on a time for a full response.

35. Gary Buehler, R.Ph., former Director of the Office of Generic Drugs ("OGD"), at CDER, noted that of 42 citizen petitions raising issues about the approvability of generic products, "very few . . . have presented data or analysis that significantly altered FDA's policies." Nevertheless, it is standard practice for FDA to withhold ANDA approval until it has completed its research into and response to a citizen petition.

36. Responding to a citizen petition strains FDA's limited resources. Regardless of a petition's merits, FDA must expend considerable resources researching the scientific, medical, legal, and economic issues that it raises, which delays ANDA approval, even if the petition is later found to be baseless.

37. Frivolous petitions sponsored by branded manufacturers have become an increasingly common tactic to delay generic competition.

J. Anticompetitive "acceleration" or "most-favored entry" clauses.

38. "Acceleration" clauses" are another weapon in the pharmaceutical monopolist's arsenal to delay generic entry. They often take the form of a "most-favored entry" (MFE) clause allowing a settling generic to enter the market earlier than otherwise agreed if certain events occur, including most commonly entry by another generic. When used to settle Hatch-Waxman litigation, MFE clauses disincentivize later generic filers from seeking to enter prior to another settling generic (such as but not necessarily the first filer) through litigation. Such clauses

constitute a disincentive to later generic filers because they accelerate the settling generic's entry date and thereby deprive the later generic of any de facto exclusivity that it might otherwise be able to obtain by entering as a result of successful litigation. An acceleration clause also transfers value to the settling generic in two ways: the contingent right to accelerate generic entry increases expected profits, and any deterrent effect on later filers protects the settling generic's market position. Because an MFE clause creates value for the settling generic, it can be used to induce the settling generic to accept a later entry date.

39. The purpose and effect of an MFE clause is to dramatically reduce any other generic manufacturer's incentive to try to enter the market before a settling generic with an MFE.. Absent the clause, other generic manufacturers would have an incentive to enter the market as soon as they were able in order to enjoy a substantial period of de facto exclusivity as the only ANDA-based generic product on the market. An MFE clause delays generic entry by, *inter alia*, eliminating this possible exclusivity because, even if the later generic succeeds in establishing its right to enter the market through litigation, it will face generic competition from the accelerated generic settler..

40. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—twice testified to Congress that "acceleration" clauses represent "the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry."[14] The clauses both induce prospective generic competitors to accept later entry dates and deter others from challenging weak patents:

[14] Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 110th Cong., at 65, 67 (2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg38992/pdf/CHRG-110hhrg38992.pdf.

> "[N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase."[15]

41. Contrary to their name, "acceleration" clauses do not in fact accelerate generic entry—they delay it. The evidence for this is conclusive. A recently published study analyzing empirical pharmaceutical settlement data concluded that "[a]n acceleration clause paired with the 180-day exclusivity period appears to effectively deter other generics and, at least in the instances we observed, never to have resulted in an actual 'accelerated' entry."[16] "Among the 54 cases in which the first filer retained sole rights to the 180-day exclusivity period, there were no cases of early generic entry. In other words, there were no cases in which the first filer's entry was accelerated, and there were no cases in which a different generic entered before the entry date set in the first filer's settlement."

V. OPERATIVE FACTS

A. Thalidomide and Lenalidomide

42. Beginning in the 1950's, thalidomide was marketed as a sleeping pill and anti-morning-sickness pill for pregnant women. Devastatingly, when consumed by pregnant women,

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[15] Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 111th Cong., at 218 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf. Apotex addressed acceleration clauses in the context in which, as here, the first-filing generic retained the 180-day exclusivity.

[16] Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, Journal of Competition Law & Economics, (2020), 16(2), 188-219, 194.

thalidomide caused life-threatening fetal deformities and birth defects. Other adverse effects included nerve damage to the patient.

43. Thalidomide was thereafter banned worldwide. The U.S. ban was in place until July 16, 1998, when FDA approved Celgene's December 20, 1996 NDA 20-785 for Thalomid, its branded version of thalidomide. FDA approved Thalomid only as a treatment for ENL, a form of leprosy.[17] To mitigate fetal exposure to the drug, FDA conditioned its Thalomid approval on Celgene's use of the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S.") distribution program, in which patients were required to review educational materials, register with the program, and agree to program restrictions. FDA noted in its Thalomid NDA approval "[t]hat current restrictions strike a balance between the need to prevent fetal exposure to the drug and the need to make the drug available without extraordinary burdens on patients and prescribers."

44. After FDA codified its REMS distribution program, FDA approved Celgene's supplemental NDA containing a proposed REMS program for Thalomid on August 3, 2010.

45. Celgene filed, prosecuted, and listed in the Orange Book one patent for the Composition of Matter for Thalomid: the '012 Patent, which was first filed with the USPTO in June 2003. Celgene filed, prosecuted and listed a total of fourteen patents related to the S.T.E.P.S. and/or REMS programs for controlling Thalomid, and later Revlimid, distribution, all of which were filed with the USPTO between August 1998 and August 2012.

46. Revlimid is an immunomodulatory agent that works against cancer cells by affecting the immune system. It is a thalidomide analogue manufactured and marketed by Celgene and later BMS. On April 7, 2005, Celgene submitted NDA 21-880 to FDA, which

[17] Thalomid was later approved in 2006 to treat Multiple Myeloma ("MM"), subject again to Celgene's restricted distribution system.

provides for the use of Revlimid to treat patients with transfusion-dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities. On December 27, 2005, FDA approved Revlimid for this indication. FDA granted Celgene five-year market exclusivity for Revlimid as a new chemical entity ("NCE") until December 27, 2010.

47. Revlimid is subject to a REMS distribution program, which initially was known as RevAssist. The primary goal of the RevAssist program is to prevent fetal exposure to Revlimid. FDA noted in its December 27, 2005 letter to Celgene that RevAssist is "an important part of the post-marketing risk management for Revlimid®."

48. All told, Celgene filed, prosecuted, and listed 30 patents in FDA's Orange Book as claiming Revlimid.

49. The Orange Book-listed patents included the '517 Patent, which was first filed with the USPTO in July 1996, and the two polymorph patents, the '800 Patent and the '217 Patent, first filed with the USPTO in September 2004 and December 2008, respectively (the "Polymorph Patents").

50. Celgene also filed, prosecuted, and listed patents in relation to the RevAssist program for controlling Revlimid distribution: the '501 Patent, the '976 Patent, the '432 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '886 Patent, and the '531 Patent, all of which were filed with the USPTO between August 1998 and August 2012.

51. Celgene also filed, prosecuted, and listed ten patents related to the dosage and methods of use for Revlimid: the '740 Patent, the '569 Patent, the '363 Patent, the '929 Patent, the '717 Patent, the '095 Patent, the '120 Patent, the '498 Patent, the '621 Patent, and the '622 Patent, all filed with the USPTO between April 2003 and September 2014.

52. Celgene obtained other patents related to thalidomide and its analogs, but did not list them in the Orange Book. Unlisted patents are not meaningful barriers to generic entry. A brand company does not have standing to sue a would-be competitor for allegedly infringing an unlisted patent *before* the competitor has actually sold its generic product. Nor do unlisted patents trigger an automatic thirty-month stay of FDA approval for the competitor's ANDA. Celgene ultimately made frivolous infringement claims for unlisted patents in response to ANDAs for lenalidomide, as discussed below.

B. Celgene's REMS and API Abuse

53. Central to Celgene's multi-faceted and decades-long scheme to unlawfully monopolize the markets for Revlimid was its REMS abuse. Celgene used its REMS distribution programs as a pretext to refuse to sell samples of Revlimid to competitors that were necessary to develop ANDAs. These actions ultimately delayed the introduction of generic Revlimid, despite the best efforts of generic competitors and warnings by FDA. Celgene's claimed business justifications for its refusals to provide samples were entirely pretextual.

54. The REMS distribution programs for Revlimid require healthcare providers and pharmacies to be certified in the RevAssist program, and patients to be enrolled, before they prescribe, dispense, or take the drugs. Prescribers and pharmacists must complete registration forms. Women of childbearing age must take a pregnancy test twenty-four hours prior to starting a course of Revlimid and at least every four weeks during their course of treatment. Prescribers must provide patients with contraception and emergency contraception counseling with each new prescription. For every new patient, prescribers must submit to Celgene a signed Patient-Physician Agreement Form that identifies the patient's risk category. The prescriber then receives a letter confirming the patients' enrollment, and the patient and prescriber receive an authorization number to be written on the prescription. The pharmacy must verify that each

prescription has an authorization number that is valid for seven days. The pharmacy must then call Celgene, obtain a confirmation number, and write this number on the prescription. The prescription is then filled within twenty-four hours. No more than a twenty-eight-day supply of Revlimid may be dispensed at one time.

55. Celgene abused its REMS program as a pretextual justification for withholding Revlimid and/or Thalomid samples from generic competitors. Among the generic manufacturers that Celgene refused to supply samples were Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, Exela Pharmsci, Inc. ("Exela") in 2006, Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009, Watson Laboratories, Inc. in 2009, Teva in 2009, and Sandoz Inc. ("Sandoz") in 2012. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr Laboratories ("Barr") from obtaining that company's thalidomide active pharmaceutical ingredient ("API").

56. Celgene's improper use of the REMS program as a pretext to refuse to provide samples is contrary to the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). FDAAA provides that "no holder of [a REMS-covered drug] shall use any element to assure safe use . . . to block or delay approval of . . . an [ANDA application]."[18]

57. Celgene's REMS distribution programs are post-marketing, commercial distribution programs. Celgene's REMS protocols do not discuss drug manufacturers conducting business with one another in the pre-marketing, drug development phase. Nor do Celgene's REMS protocols discuss or prevent distribution of samples to drug manufacturers.

58. A generic manufacturer's safety protocols are not required to be FDA-approved for the generic manufacturer to purchase samples of a REMS-subject drug. Robert West, former

[18] 21 U.S.C. § 355-1(f)(8).

Deputy Director of OGD, has commented that a generic manufacturer is not required to submit its protocols to FDA before commencing bioequivalence studies.

59. Clinical and pre-approval studies are not governed by REMS. In an August 2012 meeting with Celgene, FDA stated, "Celgene's REMS relates to a marketed situation and not a clinical trial where there is more control regarding administration of the product and the amount given is monitored and very limited."

60. A sample supply of a brand-name drug, including the API, is required to manufacture a generic equivalent. The API is used to conduct the required bio-studies and validation testing needed to be included in the generic manufacturer's ANDA.

61. Due to Celgene's REMS program, generic manufacturers were unable to purchase Revlimid samples in the United States through normal wholesale distribution channels. The restricted network that Celgene created forced incumbent competitors to purchase the drugs directly from Celgene, with FDA's endorsement.

62. Celgene's refusal to supply Mylan and other competitors with samples prompted government investigations and persistent condemnation, which occurred concurrent to Mylan's commercial and legal attempts to secure samples. FDA issued official clarifications that REMS programs should not be used for anticompetitive reasons,[19] and specifically included Revlimid (and Thalomid) on a publicly published list of brand-name drugs subject to complaints that their NDA-holder (or manufacturer) had denied access to samples to generic companies seeking to buy them. The Connecticut Attorney General's office initiated an investigation into Celgene's alleged REMS abuse relating to Revlimid and Thalomid, and wrote in January 2013 that

[19] *See* Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research).

Celgene's responses to its REMS abuse inquiry "ha[ve] raised serious concerns in my office that, notwithstanding its claims to the contrary, Celgene is not truly willing to sell Revlimid samples in a manner that would allow the BE testing necessary for a competitor to submit an ANDA….Celgene's current actions raise the specter that the discussions have been nothing but an artifice to continue to allow Celgene to delay the development of a generic alternative to Revlimid." In addition, the FTC investigated and served interrogatories on Celgene regarding its REMS abuse, wrote an amicus brief in support of Mylan's antitrust suit against Celgene, regularly testified before Congress regarding REMS abuse by Celgene and others,[20] and ultimately submitted statements to the Department of Health and Human Services ("DHHS") urging action.[21]

63. By June 2007, Mylan had begun to develop its generic Revlimid. According to internal emails from September 2007, Mylan planned to file its ANDA on December 27, 2009, was actively sourcing raw materials, had opinions on the blocking compound patents, and planned to design around the formulation patent.

[20] *Antitrust Concerns and FDA Approval Process*, Prepared Statement of Markus H. Meier, Bureau of Competition, Federal Trade Commission before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Judiciary Committee, United States House of Representatives, Washington, D.C. (July 27, 2017), https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda; *Oversight of the Enforcement of the Antitrust Laws,* Prepared Statement of the Federal Trade Commission before the Subcommittee on Antitrust, Competition Policy and Consumers Rights, Judiciary Committee, U.S. Senate (Oct. 3, 2018).

[21] *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, Statement of the Federal Trade Commission to the U.S. Department of Health and Human Services (July 16, 2018), *available at https://www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf*. ("[b]y improperly blocking the product developer from obtaining samples, the branded manufacturer can potentially delay or indefinitely block generic or biosimilar competition to its product, thereby reducing the competition that Congress specifically sought to facilitate via the Hatch-Waxman Act . . . .").

64. In early 2009, Mylan endeavored to purchase lenalidomide API to manufacture a generic version of Revlimid. Celgene engaged in delay tactics that caused Mylan to cease development efforts at various times while it attempted to procure Revlimid samples.

65. In June 2010, in response to FTC interrogatories, Celgene explained to the FTC that "Celgene has decided not to sell REVLIMID® at the present time to manufacturers."[22]

66. Over two years later, through its counsel, Celgene wrote to the FTC that it was willing to "continue selling Thalomid and begin to sell Revlimid to drug companies, branded or generic, in quantities authorized by FDA sufficient to conduct bio equivalence studies for the purpose of preparing an Abbreviated New Drug Application [ANDA] with FDA."[23] At no point prior to this email had Celgene ever sold Thalomid to generic drug companies to support BE studies for the purpose of preparing ANDAs. Celgene's letter continued: "[Celgene would] seek to set appropriate conditions with FDA for the sale of Revlimid similar to those it has set for the sale of Thalomid . . . ."

67. On August 14, 2012, Celgene wrote FDA claiming that the FDCA does not require an RLD sponsor to provide drug product to a proposed ANDA filer, and that FDA does not have authority to mandate any such requirement. Celgene even threatened that "any sale of Revlimid to a generic manufacturer will not be effectuated unless and until the FTC and the State of Connecticut Attorney General agree to close their investigation."[24]

68. On May 1, 2013, Mylan requested to purchase Revlimid samples from Celgene at market value. On May 14, 2013, Celgene wrote to Mylan that it would sell Revlimid to Mylan upon Celgene's review of Mylan's request and supporting documentation.

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[22] Exhibit to MSJ Opp., Doc No. 286-4.

[23] *Id*.

[24] Exhibit to MSJ Opp., Doc No. 285-15.

69. While not required to do so, Mylan sought FDA approval of its proposed safety protocols to avail itself of any assistance FDA might be able to offer in procuring Revlimid samples. FDA approved Mylan's protocols on July 29, 2013.

70. On March 11, 2014, Mylan wrote to Celgene explaining that it received all necessary FDA approvals. Celgene continued to refuse to provide samples, even after once again being informed of FDA approval of Mylan's proposed BE testing and safety protocols.

71. On March 20, 2014, Celgene again wrote to Mylan refusing to sell Mylan Revlimid samples. Exasperated with Celgene's tactics, Mylan sued Celgene on April 3, 2014 under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid.

72. Mylan alleged that Celgene cited safety concerns as a pretext for its continued refusal to provide samples of Thalomid and Revlimid, and that Celgene used a "playbook of obstruct[ion]" and "gam[ed] the regulatory system."[25]

73. On May 19, 2014, FDA notified Celgene that it accepted Mylan's submitted lenalidomide safety protocols and reiterated the FDCA's prohibition of the use of REMS to prevent ANDA filers from accessing drug samples.

74. The FTC filed an amicus brief in support of Mylan's suit against Celgene. The FTC noted that FDAAA was intended to prevent brand-name manufacturers from using REMS programs to impede generic competition, as Celgene was doing with Thalomid and Revlimid.

75. Further, in August 2012, the FTC sent counsel for Celgene an email detailing "a number of questions [raised] by the Bureau of Competition and the staff of the Connecticut Attorney General's office."[26]

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[25] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094 (D.N.J. Apr. 3, 2014), Dkt. No. 1 ¶8.

[26] Exhibit to MSJ Opp., Doc No. 285-16.

76. These concerns included questions about why Celgene had yet to provide samples of Thalomid to those requesting them, despite receiving explicit authorization from FDA to do so.

77. The letter also questioned what else Celgene needed to authorize the sale of Revlimid to generic manufacturers: "in the interest of advancing our discussions and trying to reach a prompt resolution with you, we propose the FTC and Celgene meet together with FDA . . . to discuss what Celgene thinks it needs from FDA in order to be able to make prompt sales to generic firms."[27]

78. In February 2013, the FTC's Bureau of Competition ("BOC") followed up on this letter with another round of correspondence.

79. In a letter to Celgene's counsel, Richard A. Feinstein, the director of the BOC stated "that there is a lot of concern here—at both the Bureau and Commission levels—about the time it has taken for your client to [redacted] of Revlimid capsules for bio-equivalence testing…the Commission's patience is wearing thin. We have reached a point where the staff may be instructed in the very near future to commence litigation."

80. Most of Mylan's claims survived Celgene's motion to dismiss. Celgene subsequently filed a motion for summary judgment. On October 3, 2018, Celgene's motion was granted in part and denied in part.[28]

81. One of Mylan's expert witnesses in that litigation, Paul J. Jarosz, Ph.D., testified that Mylan's development process was typical for the pharmaceutical industry and that "[h]ad Mylan been able to purchase Thalomid so that it could dose its bioequivalence studies and

[27] *Id.*

[28] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094, ECF No. 287, 35 (D.N.J. Oct. 3, 2018).

receive an approval for its generic drug application, Celgene's '012 Patent and claim 2 of its '327 Patent would not have prevented Mylan from launching its generic thalidomide product as the claims are invalid due to prior art and/or Mylan's formulation does not infringe them."[29]

82. Regarding generic Revlimid, Dr. Jarosz stated that "based on the simple nature of Revlimid and Mylan's previous experience developing thalidomide, it appears that Mylan could have developed and filed an application for generic lenalidomide product by December 27, 2009."[30]

83. Dr. Jarosz's report confirms that the inability of generic drug manufacturers to bring versions of Revlimid and Thalomid to market was not due to internal issues or manufacturing defects. Instead, his report reinforces the fact that the only barrier to entry in the market was Celgene's conduct.

84. Mylan never received Revlimid samples, further indicating that Celgene's refusal based on safety concerns was and continues to be a pretext used to exclude competition.

85. On August 1, 2019, Celgene announced that it reached a settlement with Mylan. On August 8, 2019, the District Court entered a consent judgment dismissing all claims with prejudice. Celgene disclosed that it agreed to pay $62 million to resolve all claims.

86. Due to Celgene's delay tactics, Mylan was not able to file an ANDA for generic lenalidomide and serve its Paragraph IV notice until November 2019.

87. Mylan's experience with the REMS process was robust and extensive, and it would have had no issues implementing a REMS program for generic thalidomide and

[29] Exhibit to MSJ Opp., Doc No. 285-21.

[30] *Id*.

lenalidomide.[31] As Jeff Fetterman, an expert hired by Mylan in its lawsuit against Celgene, opined, "Mylan has extensive experience developing, implementing, and managing risk management programs, including several REMS programs with the same or similar restrictions and requirements as the S.T.E.P.S. and RevAssist programs."[32] Mr. Fetterman continued and stated "[i]f Celgene had provided brand samples to Mylan and cooperated in developing a shared REMS program for thalidomide, the SS REMS development and FDA approval likely would have taken 18 to 24 months. Furthermore, this estimate may be conservative, as an alternative parallel agreement to sign onto the S.T.E.P.S. program would have taken even less time, possibl[y] as few as 12 months. All of this work could have begun in advance of Mylan's ANDA approval…."[33] Mr. Fetterman's report details further how Celgene's refusal to provide drug samples due to noncompliance with REMS procedures was a misdirection and stall tactic that was not based in truth or fact.

88. While Celgene claimed that safety concerns prevented it from supplying any potential ANDA sponsor with the necessary and required samples of Revlimid and/or Thalomid, it authorized its competitive intelligence firm, GBMC, to purchase, handle, and transfer thalidomide even though it had no safety training.

89. In 2003, Celgene authorized GBMC to purchase thalidomide API from a European supplier, Alan Pharmaceuticals. In fact, Celgene authorized GBMC to use undercover purchases to obtain samples of thalidomide API from various API suppliers. In an undated letter, GBMC detailed the sequence of events it used to acquire thalidomide samples outside the normal chains of distribution to satisfy Celgene's request. This sequence included falsifying

[31] Exhibit to MSJ Opp., Doc No. 286-2.

[32] *Id*.

[33] *Id*.

prescriber names and permitting GBMC (a non-pharmaceutical company without any experience handling teratogenic drug products) to handle thalidomide samples, all without a formal tracking mechanism. Celgene's Senior Director of Market Research testified in a previous litigation that he did not notify Celgene's legal department of these undercover purchases, that Celgene did not do background checks on individuals that would be handling the drug product, and that he could not recall whether the purchased product was in its proper packaging when Celgene received it, or who at Celgene received it.

90. These Celgene authorized transactions did not comport with any safety protocol.

91. Celgene willingly and frequently provided access to Revlimid and Thalomid to non-competitor research organizations for the purpose of conducting clinical studies. It provided access to such organizations outside the REMS process and without FDA guidance or approval for the safe handling of the drug products.

92. Celgene provided Revlimid for at least 3,600 different research and investigational studies, and Thalomid for over 100 investigator-initiated trials ("IIT") without requiring REMs compliance.[34]

93. For example, Celgene provided Revlimid and Thalomid to the Johns Hopkins School of Medicine for clinical trials and provided Revlimid to Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, TX.

94. An IIT process is initiated when an investigator submits a Letter of Intent ("LOI") outlining a proposal. The brand company then reviews the proposal. Here, Celgene testified that

[34] IITs are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups, cohorts or physicians.

it tried not to review the full protocol, but rather would typically review a simplified synopsis, along with the nature of the request, the budget, and the amount of drug requested. Celgene typically adjudicated such requests within two months. Its review did not require in-house counsel assistance. Celgene has never denied an IIT proposal due to fetal exposure safety concerns.

95. After approving an IIT proposal, Celgene works with the investigator to draft a study protocol and consent form to be submitted to FDA for approval. In this specific context, Celgene admitted that FDA's approval gives Celgene confidence in the safety of the trial. Celgene then supplies Revlimid or Thalomid to the investigator to initiate the study.

96. As part of its scheme to monopolize the market for Revlimid, Celgene not only refused to sell samples to its competitors, but also executed exclusive contracts with ingredient suppliers designed to delay competitors from obtaining the necessary resources to file an ANDA. As these suppliers could produce more API than Celgene required, the exclusivity provisions had no business justification and were executed entirely to deny competitors access to API, thereby foreclosing generic entry into the Revlimid market.

97. Celgene's refusal to provide samples of Thalomid and Revlimid to generic manufacturers and execution of an exclusive API supply contract were driven by the same intent rather than any good faith business rationale.

C. Celgene's Patent Misconduct

98. Celgene's efforts to delay generic Revlimid did not end once a generic manufacturer managed to obtain the samples necessary to formulate a generic and file an ANDA. Celgene further sought to delay generic Thalomid and/or Revlimid by obtaining and asserting invalid patents that it used to delay the approval of prospective generic competitors. Celgene's patents were subject to strong invalidity and unenforceability arguments, including the key

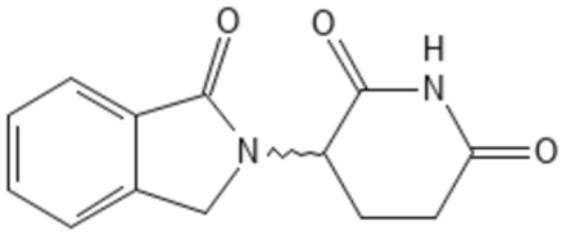
patents on which Celgene relied to exclude generic competition, namely the '517 compound patent and the polymorph patents.

99. The original, core patent for the composition of Celgene's thalidomide-derived drugs is the '517 Patent, filed in 1996. It expired on October 4, 2019. Thalidomide, the drug on which Revlimid is based, was first marketed in 1957. The innovations on which the '517 Patent is based are obvious in light of the innovations and research conducted long before Celgene began its effort to bring Revlimid and Thalomid to market; thus, the '517 Patent and the subsequent patents derived from it are invalid.

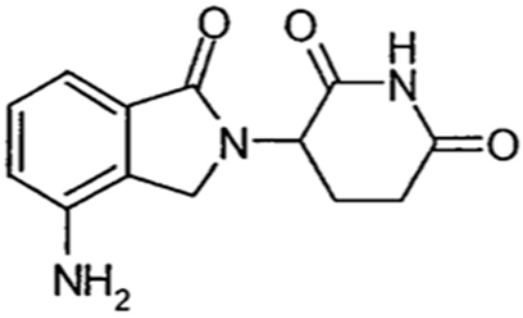
100. A person working in the relevant field would have identified thalidomide and its analogs as effective in treating a variety of conditions. It would have been a natural choice to select EM-12 and/or 4-aminothalidomide as lead compounds for further development efforts, due to their favorable properties. And, lenalidomide, the active ingredient in Revlimid, differs from these two lead compounds, EM-12 or 4-aminothalidomide, only by the addition of an amino group or the subtraction of an oxygen atom, respectively. Such modifications were obvious because a person of ordinary skill would be motivated to make these small changes to EM-12 or 4-aminothalidomide by a desire to improve stability and/or solubility. A person of ordinary skill would have had a reasonable expectation of success that such modifications would produce a compound with beneficial properties due in part to the close structural similarity of the lead compounds to the claimed compound.

101. EM-12 is structurally similar to lenalidomide, differing only in the presence of an amino group (NH_2) at the 4-position of the phthalimidine ring:

EM-12



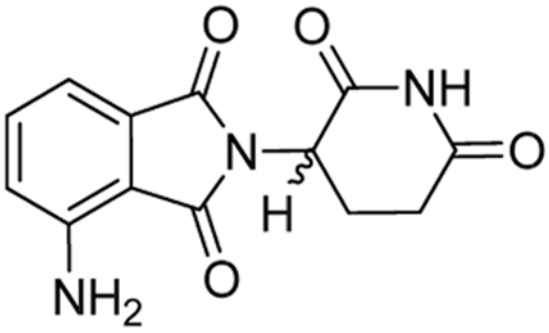
Lenalidomide[35]



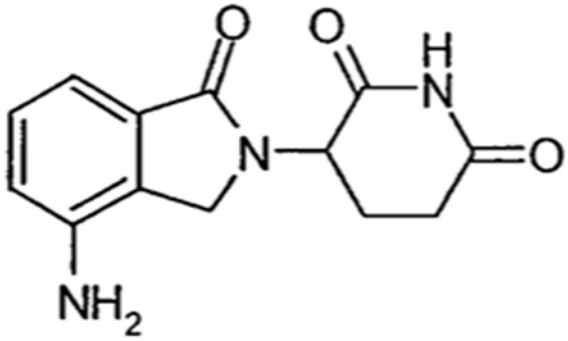
102. A person skilled in the art would be motivated to make the small structural change of adding an amino group to EM-12 at this particular location – a routine and easy change to make to the compound – as part of the standard steps in drug development and optimization.

103. 4-aminothalidomide is structurally similar to lenalidomide, differing only in that lenalidomide has one fewer oxygen atom than 4-aminothalidomide:

4-aminothalidomide



Lenalidomide[36]



104. It has been well known in the scientific community for decades that thalidomide analogs have a tendency to undergo hydrolysis (*i.e.*, degradation in the presence of water) and

[35] *See* Revlimid labeling information submitted by Celgene to the FDA at p. 5, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021880s000_Revlimid_Prntlbl.pdf

[36] *See* Revlimid labeling information submitted by Celgene to the FDA at p. 5, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021880s000_Revlimid_Prntlbl.pdf

therefore one skilled in the art would have been motivated to make the well-known modification of subtracting the oxygen atom from this location to reduce the chance of hydrolysis and thereby promote stability. Indeed, the subtraction of an oxygen atom from this location is how one would obtain EM-12 from thalidomide, with the resulting compound having a superior stability profile as compared to thalidomide.

105. A person skilled in the art would have been motivated to make these minor changes at the specified locations with a reasonable expectation of success in creating a compound with beneficial properties based on the structural similarity of the lead compounds (EM-12 and 4-aminothalidomide) to lenalidomide; the teachings of the prior art regarding known modifications to improve the compound's chemical properties (*e.g.*, stability and solubility); the nature of the small changes at issue (*i.e.,* either the addition of an amino group or the subtraction of a single oxygen atom); and the totality of the prior art on thalidomide analogues (including EM-12 and 4-aminothalidomide specifically).. Accordingly, the '517 claim for the lenalidomide compound is obvious in light of the prior art and therefore invalid.

106. The '517 Patent has ten claims. Claims 1 – 9 claim methods-of-use as to six compounds. In contrast to these method of treatment claims, Claim 10 of the '517 Patent claims four compounds, including lenalidomide. One of the method of treatment claims (Claim 8) pertains to pomalidomide. However, pomalidomide is not one of the compounds claimed in Claim 10 of the '517 Patent.

107. On April 14, 1998, Celgene filed a Request for Reexamination concerning the '517 Patent. Celgene "sought reexamination because of a question raised by a non-adversarial third party, a potential licensee, as to the significance of certain prior art." Celgene sought reexamination of claims 1-10 of the '517 Patent "in view of: (l) D'Amato, U.S. Patent No. 5,593,990 issued Jan. 14,1997; (2) D'Amato, U.S. Patent No. 5,629,327; (3) D'Amato, U.S.

Patent No. 5,712,291 (together, "the D'Amato Patents"); (4) in view of Leibovich et al. U.S. Patent No. 4,808,402 and (5) Leibovich et al., Macrophage-lnduced Angiogenesis is Mediated By Tumor Necrosis Factor-α, Letters To Nature, Vol. 329, pages 630-632, pub. 15 October, 1987" (together, the "Leibovich References").

108. On November 11, 1998, the PTO granted the request for reexamination, explaining Celgene "is correct to allege that all three of the primary references, namely, the D'Amato Patents possess the same disclosure and both of the ancillary references, namely, the Leibovich et al. Patent and Journal article possess essentially the same disclosure. . . . The requester alleges that the three D'Amato patents generically teach[] the compounds of the involved patent under reexamination and that both Leibovich et al. references may be relevant because they teach the concept of Tumor Necrosis Factors possess[ing] the unexpected ability to induce angiogenesis, which is related to the involved patent under reexamination, albeit with different compounds, which appears to have relevance. **A substantial new question of patentability affecting claims 1-10 of United States Patent No. 5,635,517 is raised by the request for reexamination**."

109. On December 9, 1998, Celgene submitted its Statement as to why the newly disclosed prior art references did not render the '517 patent invalid for obviousness, arguing: "D'Amato clearly does not describe or suggest the compounds used in the claimed method defined by claims 1-9 or those recited in claim 10. Regardless of what compounds the D'Amato patents do disclose, however, those references cannot render obvious the claimed method of reducing TNFa levels. This is also true of Leibovich et al. and D'Amato in combination with Leibovich et al. The Patent Owner sought reexamination, not because it believed D'Amato was relevant, but because of a question raised as to the significance of D'Amato by a nonadversarial third party. While D'Amato may raise a substantial new question of patentability, and should be

considered, it is submitted that the ultimate question of patentability must be resolved in the Patent Owner's favor with a finding confirming the patentability of claims 1-10. Favorable action is earnestly solicited."

110. On February 22, 1999, the PTO rejected all claims of the '517 patent as unpatentable over the three D'Amato patents (the '990, '327, and '291) and in view of the two Leibovich references, finding, "**there is ample information in the prior [art] to motivate one of ordinary skill in the chemical arts to place [applicant's] compounds in possession of the public**." Explaining its determination that the claims were unpatentable as obvious, the PTO stated:

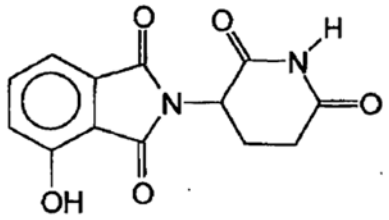
> [T]he record has shown and the patentee has admitted in the record that the 3 D'Amato patents contain the same disclosure and said D'Amato patents supra disclose the very closely analogous compounds . . and methods for their preparation. . . . there is a teaching of equivalence between hydrogen, hydroxy, epoxy and amino as possible substituents on the 4,5,6 and 7 positions of the benzene ring of the said 1-oxo- or 1,3-dioxo-isoindoline ring. The concept of angiogenesis and administering said reference compounds to a patient with toxic concentrations of TNF-α is taught [in the D'Amato patents]. The [Leibovich references] represent an excellent reference for the known compound "thalidomide" which represents activation of macrophages, their relationship to angiogenic activity and a method of controlling abnormal concentrations of TNF-α factor associated with solid malignant tumors, benign tumors, leukemias and the like. . . . Since the properties of the prior art overlap with the ['517] under reexamination, and the 3-D'Amato patents teach the equivalents of hydrogen, hydroxy, epoxy and amino groups as substituents on each of the four positions on the benzene ring of the isoindoline nucleus, there is ample information in the prior [art] to motivate one of ordinary skill in the chemical arts to place applicants compounds in possession of the public.

111. On February 25, 1999, Celgene submitted a Request for Reconsideration and attached a declaration from Dr. David I. Stirling, Celgene's then-Chief Scientific Officer and Executive Vice President (the "Stirling Declaration"). Celgene argued that any finding of

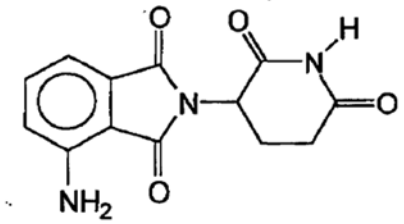
obviousness was rebutted by the evidence of "unexpected properties" set forth in the Stirling Declaration.

112. The Stirling Declaration states in part: "Tests were conducted under my supervision to evaluate the relative activities of test compounds to inhibit the levels of [TNF-alpha]. . . . These tests were conducted on various compounds including the following:

Compound 1:



Compound 2:



113. The Stirling Declaration further stated: "I conclude that Compound 2 is >10,000 fold more active than Compound 1 in this primary human cell-based assay."

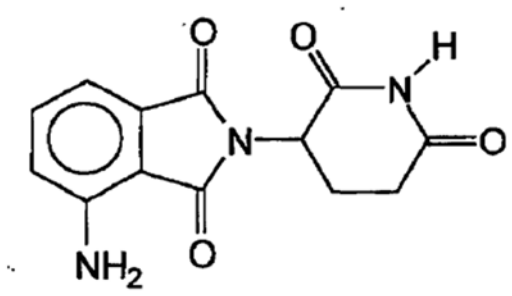
114. In its accompanying Request for Reconsideration, Celgene explained Dr. Stirling's findings, stating: "As explained by Dr. Stirling, Compound 2 was >10,000 fold more active than Compound 1 in this assay. Compound 1 of course is the hydroxythalidomide compound of D'Amato; ***Compound 2 is the corresponding amino compound of the present claims***." Celgene concluded, "it is submitted that the D'Amato patents, alone or in combination with the Leibovich *et al.* patent and publication, do not establish a *prima facie* case of obviousness. If, however, these references are deemed sufficient to establish a *prima facie* case

of obviousness, it is believed the same has been fully rebutted by the evidence of record demonstrating unexpected properties."

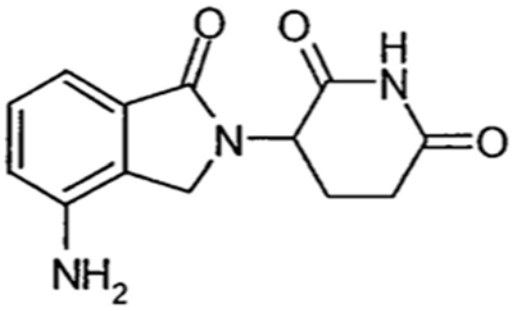
115. Shortly after Celgene's submission of the Request for Reconsideration and the Stirling Declaration, the PTO issued a Notice of Intent to Issue Reexamination Certificate allowing the claims of the '517 patent.

116. However, "Compound 2" is not lenalidomide, nor is it any of the other compounds claimed by the '517 patent. "Compound 2" is another thalidomide analogue, pomalidomide, which is not one of the compounds claimed by the '517 patent.

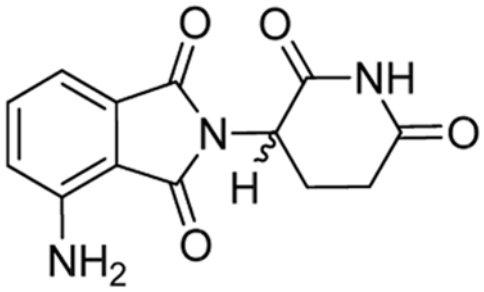
Compound 2:



Lenalidomide[37]



Pomalidomide[38]



[37] *See* Revlimid labeling information submitted by Celgene to the FDA at p. 5, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021880s000_Revlimid_Prntlbl.pdf

[38] *See* Pomalyst labeling information submitted by Celgene to the FDA at p. 10, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204026Orig1s000Lbl.pdf

117. As shown above, lenalidomide has one fewer oxygen atom as compared to "Compound 2" referenced in the Stirling Declaration. The Stirling Declaration does not describe the testing of lenalidomide, or any of the other three compounds claimed by Claim 10 of the '517 patent.

118. "Compound 2" is in fact pomalidomide, which is mentioned in Claim 8 of the '517 patent as part of a method of treatment claim, *i.e.,* "The method according to claim 7 in which said compound is 1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline." But the testing of "Compound 2" was irrelevant to the ***compound patent claims*** in Claim 10 of the '517 patent. Celgene misled the PTO and breached its duty of candor by, *inter alia,* submitting testing that had nothing to do with the most vital part of the '517 patent, *i.e.,* the compound claims of Claim 10.

119. Dr. Stirling states in his declaration that he performed testing on "various compounds." Yet, Dr. Stirling presented his findings with respect to only one comparator, *i.e.*, "Compound 1," which is a compound identified in the D'Amato patents. Celgene concealed the rest of the data; Celgene cherry-picked the results that would best support its claim of unexpected results.

120. In sum, the '517 patent is invalid. After Celgene submitted the D'Amato and Leibovich references to the PTO as part of the reexamination, the PTO rejected all claims of the '517 patent as invalid over the prior art. To overcome those obviousness rejections, Celgene submitted testing that purportedly showed unexpected results. However, the "unexpected results" did not pertain to any of the compounds claimed by the '517 patent. Celgene failed to overcome the PTO's finding of obviousness, and the compound claims of the '517 patent are therefore invalid.

121. That Dr. Stirling intended to deceive the PTO is supported by the facts that: (i) he had detailed first-hand knowledge of Celgene's thalidomide analogue testing program generally, including the testing that had been done as to lenalidomide and related analogues, as well as the results of that testing program, (ii) he did not submit all of the testing results relevant to the issues raised during the '517 patent examination, and (iii) he chose to present testing regarding a compound *other than* one of the compounds claimed by the '517 patent (i.e., other than the compounds that would have supported allowing reexamination) in support of patentability.

122. At a minimum, the '517 patent would have been found invalid by a court. The same facts would also support a finding of inequitable conduct by David Stirling (who signed and submitted the declaration) and potentially Celgene's in-house and outside counsel who submitted the Request for Reconsideration and supporting Stirling Declaration (Bruce M. Collins) and/or otherwise prosecuted the reexamination.

123. Celgene was able to overcome the PTO's conclusive findings of obviousness only by submitting the fraudulent Stirling Declaration. That declaration falsely stated that a compound claimed in the '517 patent was surprisingly at least 10,000 times more active than hydroxythalidomide when, in fact, the tested compound was not even one of the four compounds claimed in the compound claim in the '517 patent.

124. To extend its monopoly on the sale of lenalidomide, Celgene began filing additional patent applications seeking to claim other polymorphic forms of lenalidomide. Polymorphs, also known as solvates or crystalline forms, of previously patented compounds are routinely developed as a standard practice in the pharmaceutical industry, according to a US patent examiner in a rejection of one of Celgene's polymorph patent applications, and generally are not separately patentable.

125. Nonetheless, Celgene managed to get the USPTO to approve its polymorph patents and list them in the Orange Book. These patents—the '800 Patent and the '217 Patent—expire in 2027 and 2024, respectively. Since these patents have the latest expiration dates of any patents associated with Revlimid, they have been key patents cited in repeated attempts by Celgene and BMS to block generic competitors from the market.

126. Celgene and BMS have repeatedly settled lawsuits brought on these polymorph patents instead of testing their strength in court for fear of the result. When Natco filed an ANDA for a generic version of lenalidomide in September 2010, Celgene brought suit against it and its marketing partners, Watson and Watson's subsidiary Arrow, claiming infringement.[39] The parties agreed to a *Markman* hearing to settle the meaning of disputed patent terms. Citing Celgene's own clarified definition of the term "hemihydrate," Natco amended its invalidity contentions to the '800 Patent, arguing that it was invalid for indefiniteness, lack of enablement, and lack of written description. When Celgene was unable to prevent Natco from raising these amended invalidity contentions, Celgene quickly settled with Natco with an anticompetitive reverse payment settlement agreement, described more fully *infra* Section VII.E. Having learned a dangerous lesson, Celgene did what was necessary to avoid a similar *Markman* hearing to address the meaning of "crystalline" in its subsequent litigation against Dr. Reddy's and other generic manufacturers.[40]

127. Celgene knew that the overbroad terms of its redundant polymorph patents were insufficient to block generic competitors from bringing non-infringing products to market where

[39] *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982 (D.N.J. Jul. 9, 2015). Celgene alleged that while Natco Pharma filed the ANDA, Arrow assisted Natco Pharma in preparing and filing the ANDA, and Watson prosecuted the ANDA before FDA.

[40] Letter to Court, *Celgene Corp. v. Dr. Reddy's Laboratories Ltd.*, 2:16-cv-7704 (D.N.J. Mar. 23, 2018), ECF No. 77. On the date that its responsive *Markman* pleadings were due, Celgene filed a letter informing the court that it resolved its claim construction disputes with Dr. Reddy's and would not be filing responsive pleadings.

the generic manufacturer had developed a suitable workaround to Celgene's patents. The claims of Celgene's other polymorph patent, the '217 Patent, also identify crystalline and hemihydrate forms of lenalidomide and are invalid for the same reasons as the '800 Patent. Celgene has entered stipulations dismissing claims based on the '217 Patent and/or executed a covenant not to sue on the '217 Patent in actions against eight separate generic manufacturers.[41] As a result, Celgene has shielded the '217 Patent, and the patents derived therefrom, from judicial scrutiny and invalidation. Nonetheless, Celgene continues to sue generic rivals on the '217 Patent solely to delay generic entry.

128. These patents, like the '517 Patent from which they were derived, were obtained only because the applicants failed to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent. Celgene's failure to disclose such prior art provides an independent basis for invalidity. The polymorphs are also obvious variants of the composition of matter patent, adding a further basis for invalidity. Finally, based on Celgene's representations in the *Markman* hearing held in the *Natco* litigation, the claims of the patent are unenforceable as overbroad.

129. The '501 and '720 patents covering Celgene's REMS program on Thalomid and Revlimid were invalidated by the Patent Trial and Appeal Board ("PTAB") on October 26,

[41] *See* Statement, *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197, ECF No. 140 (D.N.J. Aug. 31, 2012); Statement, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 81 (D.N.J. Aug. 8, 2018); Statement, *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-02528, ECF No. 93 (D.N.J. Aug. 8, 2018); Stipulation and Order of Dismissal, *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163, ECF No. 63 (D.N.J. Aug. 16, 2018); Statement, *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:18-cv-11630, ECF No. 50 (D.N.J. Jan. 22, 2019); Consent Judgment, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 63 (D.N.J. Apr. 30, 2019); Stipulation and Order of Dismissal, *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2:18-cv-17463, ECF No. 54 (D.N.J Jan. 21, 2020); Statement, *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003, ECF No. 120 (N.D. W. Va. Oct. 9, 2020).

2016.[42] Celgene's other REMS patents are also invalid. Celgene stopped pressing its other REMS patents in litigation against generics after the Federal Circuit affirmed the PTAB decision.

D. Celgene's Citizen Petition Abuse

130. As part of its decades-long scheme to monopolize the market for Revlimid, Celgene filed baseless citizen petitions against generic manufacturers when manufacturers managed to secure the necessary API to file an ANDA. In filing such citizen petitions, Celgene knew that it is the standard practice for FDA to withhold ANDA approval until FDA completes its research into and response to a citizen petition. The filing of baseless citizen petitions occurred often in tangent with, and as a complement to, Celgene's sham patent litigations.

131. To illustrate, Celgene filed a citizen petition on September 20, 2007, urging FDA not to approve Barr's thalidomide ANDA. Celgene submitted this citizen petition one year after Barr had filed its ANDA with FDA for generic Thalomid and nine months after Celgene had filed a sham patent lawsuit. Celgene's citizen petition was baseless and intended to delay Barr's entry into the market for generic thalidomide.

132. In its citizen petition, Celgene requested that FDA withhold approval of any generic thalidomide product, or alternatively: i) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R. Part 314; and ii) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for, and registering patients with, multiple myeloma, in violation of Celgene's orphan drug exclusivity, which would expire in 2013.

[42] See *Coalition for Affordable Drugs VI LLC, et al., v. Celgene Corp.*, IPR2015-01092, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01092; IPR2015-01096, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01096; IPR2015-01102, Paper No. 75 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01102; IPR2015-01103, Paper No. 76 (Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01103 ("*Coalition*").

133. Celgene's petition was meritless. It lacked any reasonable regulatory, scientific, medical, or other basis. FDA lacked statutory authority to withhold approval of generic thalidomide on the bases given by Celgene or to require the actions Celgene requested. Like its litigation against Barr, this citizen's petition was a sham designed to maintain Celgene's monopoly.

134. On December 19, 2008, Barr responded to the petition, arguing that it "is nothing more than yet another attempt by a brand company to block all generic competition using market exclusivity protecting just a single approved indication."[43] Barr explained that Celgene's pretextual safety concerns were "hyperbole designed to improperly play on the public's fears regarding thalidomide," and that Barr's proposed thalidomide would be safe and its label would contain all precautionary information contained in the Thalomid label. Specifically, Barr argued that the law permits it to carve-out from its label Thalomid's protected MM indication, and that "Barr's Thalidomide Labeling Need Not Contain The Multiple Myeloma Indication To Ensure The Safe And Effective Use Of The ANDA Product."

135. Nearly six years later, on September 30, 2014, FDA denied Celgene's citizen petition. Specifically, it "den[ied Celgene's] request that FDA decline to approve any ANDA for thalidomide."

136. Celgene's filing of baseless citizen petitions was part of, and advanced, its scheme to monopolize the market for Revlimid.

E. Celgene's Patent Litigation

137. In addition to the abuses outlined above, Celgene brought serial patent litigation against its generic competitors without regard to the merit or likely outcome of those lawsuits,

[43] Exhibit to MSJ Opp., Doc. No. 285-17.

simply to obtain the benefits of the 30-month stay of FDA approval. Many of those lawsuits were ultimately settled by means of unlawful reverse payments. As described in more detail below, Celgene, Natco and Natco's marketing partners executed an unlawful reverse-payment/output-restriction/market-allocation agreement regarding Revlimid in 2015. Partly as a result of the MFE included in that agreement, Celgene induced numerous later-filing generics to enter into similar settlement agreements to fulfill the expectations of the parties to the initial Natco agreement.

138. To date, after fifteen years of litigation comprising at least 28 separate actions, Celgene and BMS have not allowed a single patent to face judicial scrutiny and judgment in a trial before a district court. Only a single remaining patent litigation, against Alembic, remains pending.

139. In 2010, Celgene filed a patent lawsuit against Natco for its lenalidomide ANDA. In 2016, Celgene filed a patent lawsuit against Dr. Reddy's for its lenalidomide ANDA. In 2017, Celgene filed patent lawsuits against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, "Zydus"), Cipla Ltd. ("Cipla"), Lotus Pharmaceutical Co., Ltd. and Alvogen Pine Brook, LLC (collectively, "Alvogen"), and again against Dr. Reddy's for their lenalidomide ANDAs. In 2018, Celgene filed patent lawsuits against Apotex Inc. ("Apotex"), Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero Drugs Ltd., and Hetero USA, Inc. (collectively, "Hetero"), twice against Sun Global FZE, Sun Pharma Global Inc., Sun Pharmaceuticals Industries, Inc., and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"), again against Alvogen, Dr. Reddy's, Cipla, and Zydus for its lenalidomide ANDAs. In 2019, Celgene filed patent lawsuits against Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (collectively, "Mylan"), and again against Cipla, Hetero, and twice against Apotex. In 2020, Celgene filed patent lawsuits against Lupin Ltd. ("Lupin"), and again against Mylan and Hetero. In 2021, Celgene filed patent

lawsuits against Hikma Pharmaceuticals USA, Inc. ("Hikma"), Aurobindo Pharma Ltd., Eugia Pharma Specialties Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo"), Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent"), Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. (collectively, "Biocon"), Lupin Ltd., and Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, "Alembic").

140. In each case, Celgene alleged that the proposed generic versions of Revlimid infringed Celgene's patents. Each generic defendant counterclaimed, alleging that Celgene's patents were invalid as anticipated or for obviousness, or for lack of written description, under 35 U.S.C. §§ 101, 102, 103 and/or 112, and general principles of patent law, and/or were not infringed. Because Celgene knew that its patents were invalid, it also must have known that the litigation to enforce the invalid patents would be unsuccessful. Celgene brought the actions only because doing so would delay generic entry.

141. As detailed above, Revlimid was one of the key assets acquired by Bristol-Myers Squibb in its acquisition of Celgene on November 20, 2019. Beginning in November 2019, BMS adopted and ratified the prior unlawful actions taken by its wholly owned subsidiary and became a party in its own right to the continuing conspiracy in restraint of trade and scheme to monopolize alleged in this Complaint.

F. The *Natco* Litigation and Settlement

142. On August 30, 2010, Natco sent a Paragraph IV certification letter to Celgene, which contained a detailed factual and legal statement as to why Celgene's REMS patents, and the '517, '230, '554, '106, and '800 patents, were invalid, unenforceable, and/or not infringed by Natco's proposed generic Revlimid.

143. Shortly thereafter, in September of 2010, Natco filed the first ANDA seeking approval to bring lenalidomide capsules to market in the 5 mg, 10 mg, 15 mg, and 25 mg strengths.

144. On October 8, 2010, Celgene filed a patent infringement suit against Natco in the District of New Jersey.[44]

145. Celgene continued to pursue new patents for its Revlimid product. In 2012, it listed two new patents in the Orange Book, a formulation patent (patent no. 8,288,415) and another REMS patent (patent no. 8,315,886). In response, Natco sent Celgene an additional Paragraph IV certification on March 14, 2013 which contained a detailed factual and legal statement as to why the '415 and '866 patents were invalid, unenforceable, and/or not infringed by Natco's generic Revlimid product.

146. On April 10, 2013, Celgene caused patent no. 8,404,717 to be listed in the Orange Book for Revlimid. The '717 patent is a method of use patent for the treatment of myelodysplastic syndromes using lenalidomide.

147. Celgene filed a Fifth Amended Complaint against Natco on May 6, 2013.[45] Celgene alleged that Natco's generic Revlimid product would infringe the Revlimid REMS patents, as well as the '886 patent, the '517, '230, '554, '106, '800, '415, '717 and '598 patents. Natco denied these allegations and argued that the '517, '230, '554, '106, '800, '415, '717 and '598 patents were invalid and that its proposed generic lenolidamide product did not infringe Celgene's '800 Patent because Natco's proposed generic product did not contain lenalidomide

[44] Complaint, *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197 (D.N.J. Oct. 8, 2010).

[45] Amended Complaint (Fifth), *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197, ECF No. 215 (D.N.J. May 6, 2013).

hemihydrate. Natco also filed counterclaims alleging invalidity and unenforceability of Celgene's patents.

148. Meanwhile, Celgene abandoned its efforts to assert many of its ill-gotten and invalid patents. On January 20, 2011, Celgene informed the court that it covenanted not to sue Natco on the '326 Patent and '432 Patent.[46] On August 31, 2012, Celgene did the same for the '217 Patent, which, along with the '800 Patent, is one of Celgene's two key polymorph patents.[47] And on September 26, 2012, Celgene covenanted not to sue Natco on the '763 Patent.[48] In exchange, Natco dropped its counterclaims of invalidity against Celgene.

149. The court conducted a *Markman* hearing on May 15, 2014. On May 27, 2014, the Hon. Susan D. Wigenton issued a *Markman* Opinion resolving disputed claim definitions in Natco's favor on three of the five disputed terms at issue.[49] The rulings included narrow constructions of certain claim terms of the '554, '230, '357, and '598 patents, likely permitting Natco to prevail on a noninfringement theory as to these pharmaceutical patents ('554 and '230 Patents) and polymorph patents ('357, and '598 Patents). Indeed, after issuance of the *Markman* Opinion, Celgene stipulated to the dismissal of the '554 and '230 patents.

150. Natco's strategy also included an attack on the '800 and '217 Patents, two polymorph patents that expire in 2027 and 2024, respectively.[50] As discussed above, these patents are invalid for obviousness. Nonetheless, Natco also alleged that it had invented around these patents. The polymorph patents, including the '357 and '598 Patents, claim multiple

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[46] Statement, *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197, ECF No. 24 (D.N.J. Jan. 20, 2011).

[47] *Id.* at ECF No. 140 (D.N.J. Aug. 31, 2012).

[48] *Id.* at ECF No. 145 (D.N.J. Sep. 26, 2012). In its Answer, Natco provided twenty-six pages of prior art references rendering the '763 Patent invalid and/or unenforceable. 2:12-cv-04571, ECF No. 15, Exh. B (D.N.J. Sep. 28, 2012).

[49] *Markman* Opinion, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 6, 2013), ECF No. 312.

[50] As above, Celgene covenanted not to sue on the (earlier expiring) '217 patent.

different polymorph embodiments of lenalidomide, which are labeled "Form A," "Form B," all the way through "Form H," The different polymorph embodiments differ based upon their levels of solvation or hydration. For instance, Form A is "unsolvated" and Form B is "hemihydrated." They also differ based upon specific testing results (such as X-Ray powder diffraction) that serve as "finger prints" or identifying characteristics of each different polymorph.

151. Celgene argued that these embodiments were not claimed, specific polymorphs, but merely exemplars. In arguing for this (rejected) construction, Celgene's counsel revealed how difficult it would be for Celgene to prove infringement if specific polymorphs were claimed by listing the numerous specifications that an ANDA would need to have: "This is what they're talking about reading in. So I don't know how you would put the chart in there, but you'd have to put words to it. And they'd have another one, and another one, and another one, and another one, and another one, and another one, and another one, and another one, and it's just keeps going. This is all the material they are suggesting should be read into this claim, this term, to define Form A. My finger is getting tired, but I'm almost done. This is what is the claim would look like with - and it's not even all of it because we couldn't fit it on one slide."[51] In other words, unless Natco (or another generic's) product had *each* of the innumerable characteristics, it would not infringe.

152. The Court rejected Celgene's attempt, limiting "Form A to mean a particular polymorph with these distinguishing characteristics." This cleared the way for Natco to prevail on noninfringement where its ANDA did not exhibit *each and every* characteristic specified of the disclosed polymorph forms – an unlikely proposition as demonstrated by Celgene's own arguments at the *Markman* hearing.

[51] Transcript, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 20, 2014), ECF No. 310, at 84.

153. Additionally, the '800 Patent included the disputed term "hemihydrate." Natco argued that the term required an exact water to compound ratio of 0.5 to 1, which would have further limited the claimed polymorphic crystal form to what is called "Form B." Celgene argued that "hemihydrate," as used in the patent, implied an *approximate*, rather than exact, ratio. Under either construction, Natco's accused products *do not infringe* because they are an "anhydrous" form, i.e., a *form that has no water* in the crystal.

154. In the Court's *Markman* Opinion, the Court adopted Celgene's proposed definition, reading "hemihydrate," as a term of approximation.[52] Nevertheless, Celgene could only prove infringement of Natco's anhydrous product by arguing that *at some point* (such as after ingestion) Natco's product *would become* hemihydrated and infringe. However, by arguing for this broader definition of hemihydrate to bolster its weak and speculative infringement argument, Celgene exposed the '800 Patent to new invalidity defenses.

155. Less than a month after the *Markman* hearing, Natco moved to amend its answer to add invalidity of the '800 patent for indefiniteness, lack of written description, and lack of enablement.[53] It argued that in light of the Court's definition reading "hemihydrate," as an approximation: (1) a person of ordinary skill would be unable to determine the scope of the patent, (2) the patent did not disclose or suggest to a person of ordinary skill in the art that any hemihydrate form of lenalidomide other than Form B even exists, let alone clearly convey that the patentee was in possession of other hemihydrated forms of lenalidomide, and (3) the patent

[52] *Markman* Opinion, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 27, 2014), ECF No. 312, at 6-7 (defining hemihydrate to mean "a hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate").

[53] Letter, 2:10-cv-05197, ECF No. 321 (D.N.J. June 19, 2014).

does not disclose how to make a hemihydrated form, other than Form B, having the claimed characteristics.[54]

156. Celgene vigorously opposed Natco's motion in a July 11, 2014 brief.[55] When Magistrate Judge Arleo granted Natco's motion,[56] Celgene immediately appealed the Opinion and Order, which would have ultimately required Celgene to answer the invalidity issues its own claim construction had created. Briefing on the appeal of the order granting the amendment extended into January 2015 before Judge Wigenton.

157. Meanwhile, Celgene stipulated to dismissing its claims and defenses as to the '230 and '554 patents (following the Court's adoption of Natco's proposed claim terms regarding these patents), as well as the '106 and '415 Patents.[57]

158. On July 9, 2015, Judge Wigenton affirmed Magistrate Judge Arleo's Opinion and Order granting Natco's motion to amend to assert the new defenses created by the court's *Markman* Opinion.[58] The parties served expert reports in late summer 2015 and responsive expert reports in September 2015.[59] Shortly thereafter, some six years after litigation began, Celgene settled with Natco avoiding scrutiny of the infringement or invalidity of any of its patents.

159. On December 22, 2015, Celgene announced the settlement of litigation with Natco and its marketing partners Watson and Arrow International Limited ("Arrow") relating to

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[54] *Id.* at 3.

[55] Letter, 2:10-cv-05197, ECF No. 331 (D.N.J. July 11, 2014).

[56] Opinion, 2:10-cv-05197, ECF No. 366 (D.N.J. Nov. 18, 2014).

[57] Stipulation of Dismissal, 2:10-cv-05197, ECF No. 402 (D.N.J. March 26, 2015).

[58] Opinion, 2:10-cv-05197, ECF No. 440 (D.N.J. July 9, 2015).

[59] *See* Amended Scheduling Order, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 6, 2013), ECF No. 449.

Celgene's Revlimid patents. Watson and its subsidiary were subsequently acquired by Teva. Natco's ANDA for generic Revlimid was finally approved by the FDA in March 2021. Teva launched Natco's generic Revlimid a year later, in March 2022, pursuant to the terms of the unlawful December 2015 settlement agreement between Celgene and Natco.

160. At the time of the settlement, Celgene faced a substantial probability that Natco's lenolidamide product would be adjudged non-infringing, Celgene's patents would be invalidated, and/or Natco would launch its Revlimid generic "at risk." To avert the loss of its monopoly of lenolidamide products, Celgene bought off its would-be competitor, Natco.

161. The settlement agreement between Celgene, Natco, Watson, and Arrow included an anticompetitive reverse payment from Celgene to Natco, Watson, and Arrow. Celgene granted Natco and Watson a license to sell generic Revlimid beginning in March 2022 with an MFE clause, but only if Natco agreed to convert no more than 7% of the Revlimid market to generic units in the first year of its launch. The agreement gradually increases the percentage of the market that Natco may capture each year until January 31, 2026, when the agreement expires. Thus, under the agreement, Celgene and Natco agreed to delay full-fledged generic competition until at least January 31, 2026. This agreement was both a reverse-payment agreement and a horizontal agreement to restrict output and allocate markets—a *per se* violation of the Sherman Act.

162. By both the terms and effect of the arrangement, Celgene agreed to share its monopoly rents with Natco as a *quid pro quo* for Natco's agreement to limit its share of the Revlimid market and to delay full competition until at least January 31, 2026. These terms guaranteed Natco a limited share of the market at supracompetitive prices. But for the reverse payment, Celgene and Natco would have agreed to an entry date no later than some time in 2019.

163. On December 22, 2015, Celgene announced:

> In settlement of all outstanding claims in the litigation, Celgene will permit entry of generic lenalidomide before the April 2027 expiration of Celgene's last-to-expire patent listed in the Orange Book for REVLIMID®. Celgene has agreed to provide Natco with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the United States beginning on January 31, 2026. In addition, Natco will receive a volume-limited license to sell generic lenalidomide in the United States commencing in March 2022. The volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025, and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license under this agreement.[60]

164. The "mid-single-digit percentage" referred to in the release was in fact 7%.

165. Celgene and Natco kept the details of the payment terms secret from the Court, the public, and Plaintiffs.

166. On a February 12, 2016 earnings call, Natco further disclosed that the license referred to by Celgene in its announcement was royalty free. Natco also disclosed the inclusion of an acceleration clause, allowing for earlier Natco entry triggered by the early introduction of other generic versions of lenalidomide.[61]

167. Individually and collectively, these payment terms are anticompetitive. First, the volume-limited royalty-free license restricts output and allocates the market by eliminating

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[60] Press Release, *Celgene Settles REVLIMID Patent Litigation,* dated December 22, 2015, available at https://www.businesswire.com/news/home/20151222005986/en/ (last accessed October 18, 2022).

[61] *See* Natco Pharma Q3 FY 2016 Earnings Conference Call" February 12, 2016, *available at* https://natcopharma.co.in/wp-content/uploads/2016/02/NirmalBang-NatcoPharma-Feb12-2016.pdf ("… if something triggers a launch date earlier than 2022 so the agreement has standard accelerated clauses with respect to everything, so if such an event were to happen so it is 22 limited quantity which will increase over a period of time to unlimited quality till 26 or in the event that something happens to the patents or certain events which are defined in our agreement, there are whole slew of events that are defined, standard accelerated clauses kick in which allows us an earlier entry as well.").

Natco's incentive to compete on price in order to increase volume, ensuring that generic prices would remain at supracompetitive levels even after generic entry. As Teva (Natco's marketing partner) explained in an earnings conference call, the settlement with Celgene set up a "profit share."[62] The royalty-free generic license plus the MFE constitutes a large reverse payment from Celgene to Natco and Teva worth hundreds of millions of dollars. The MFE clause also deters other generics from continuing to challenge Celgene's patents and provides assurance to Natco that it will receive the most favorable entry date and retain its lucrative exclusivity period.

168. The terms of the unlawful agreement also eliminated any incentive of Celgene (and later BMS) to introduce an authorized generic, since launching an AG would simply convert brand purchases to generic purchases and defeat the purpose of the 7% limit.

169. Natco executives celebrated the profits it planned to make from the Revlimid settlement to investors:

> Revlimid looks like a blockbuster. If you look at the guidance that they have given they have given ***very obscene numbers on how big the brand will be***, right now it is about 3.5 billion. I have seen projections in the US and globally I think it is doing 5, 6 billion, they are saying it will be a $8, $9 billion brand so I think it will stay and I am still very positive about it . . . .[63]

G. Subsequent Litigation and Settlements

170. Celgene settled at least four later patent infringement suits against generic companies on terms that were consistent with and carried out the intentions of the parties to the initial Natco agreement. As explained further below, virtually all of the terms of the later generic settlements have been concealed from the public. None of the Later-Filing Generics entered the market before the March 2022 date agreed to in the initial Natco settlement. Celgene's actions in

[62] *See* "Q1 FY 2019 Teva Pharmaceutical Industries Ltd. Earnings Conference Call" May 2, 2019, *available at* https://www.fool.com/earnings/call-transcripts/2019/05/02/teva-pharmaceutical-industries-limited-teva-q1-201.aspx.

[63] *Id.* at 20.

settling these other ANDA litigations served to preserve the ill-gotten gains and market allocation with Natco, by, in part, ensuring that other generics accepted Natco's March 2022 entry date (and did not try to leapfrog over Natco to enter earlier with their own product) and forestalling robust generic competition until at least January 31, 2026.

171. As part of its unlawful anticompetitive strategy, Celgene filed three serial patent infringement suits against Dr. Reddy's for the sole purpose of delaying generic entry into the lenalidomide market. But for Celgene's anticompetitive scheme, Dr. Reddy's would have gained FDA approval far earlier and launched a competing generic Revlimid.

172. First, on September 9, 2016, generic manufacturer Dr. Reddy's sent Celgene a Paragraph IV certification notifying Celgene that it had filed ANDA No. 209-348 with the FDA seeking approval to market generic Revlimid. On October 10, 2016, Celgene sued Dr. Reddy's in the District of New Jersey.[64] Celgene later sued Dr. Reddy's in two additional suits alleging infringement of Celgene's later-acquired patents.[65] Dr. Reddy's answered, in all three litigations, that the patents asserted were not duly or lawfully issued.[66]

173. The parties filed a Joint Claim Construction Hearing and Statement on October 26, 2017, in which Dr. Reddy's notified the court that "the construction of the claim term 'crystalline' will be 'most significant to the resolution of the case' and 'will be case or claim dispositive or substantially conducive to promoting settlement,' at least with respect to the '800 and '217 patents on crystalline lenalidomide."[67] Although the '800 and '217 patents are invalid

[64] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-07704 (D.N.J).

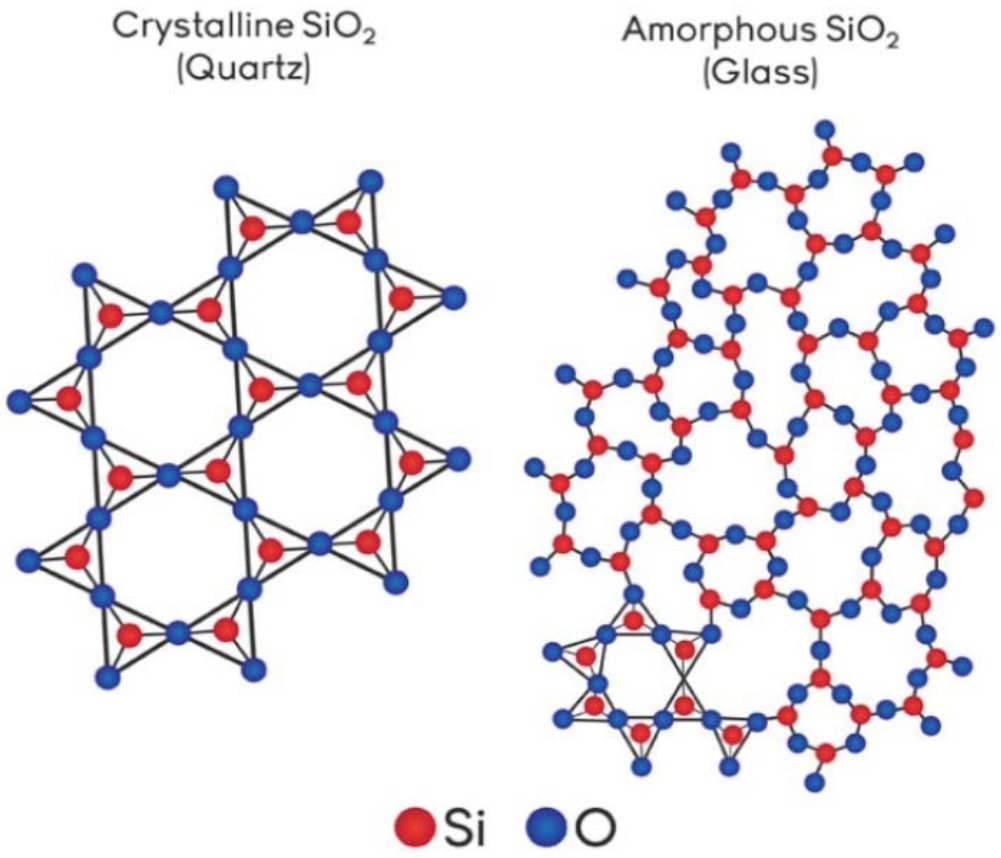
[65] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, 2:17-cv-05314 (D.N.J.); and *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, 2:18-cv-06378 (D.N.J.).

[66] *See* No. 2:16-cv-07704, ECF No. 7 (D.N.J. Nov. 18, 2016); 2:17-cv-05314, ECF No. 17 (D.N.J. Oct. 18, 2017); 2:18-cv-06378, ECF No. 30 (D.N.J. May 31, 2018).

[67] No. 2:16-cv-07704, ECF No. 57, at 4-5 (D.N.J. Oct. 26, 2017).

for obviousness, Dr. Reddy's invented around these keys patents (set to expire in 2024 and 2027) and its ANDA did not infringe Celgene's patents.

174. As detailed in its *Markman* brief, Celgene's Polymorph patents claim a "crystalline lenalidomide," but Dr. Reddy's ANDA product had an "*amorphous* lenalidomide" structure. Based on "the intrinsic and extrinsic record, as well as the understanding of the person of skill in the art," Dr. Reddy's argued that amorphous structures "are not crystalline," but rather "composed of randomly oriented molecules with no long-range order."[68]



175. This distinction, likely establishing noninfringement, was further highlighted by the patents' prosecution history. Celgene initially attempted to include claims covering

[68] No. 2:16-cv-07704, ECF No. 67, at 1, 4 (D.N.J. Dec. 22, 2017) .

amorphous as well as crystalline forms, but, following rejection by the examiner, Celgene cancelled and removed the amorphous claims from the application.[69]

176. Celgene initially opposed Dr. Reddy's proposed construction. However, following briefing, on March 23, 2018, Celgene notified the court that the parties had resolved their claim construction disputes and would not be filing responsive *Markman* briefs.

177. On information and belief, Celgene conceded Dr. Reddy's construction of "crystalline," paving the way for Dr. Reddy's to argue that its ANDA did not infringe Celgene's key Polymorph, patents because had Celgene opposed Dr. Reddy's construction (as in the *Natco* litigation), it would have opened its patents up to strong invalidity arguments.

178. In PTAB proceedings, Dr. Reddy's also previewed winning invalidity arguments regarding Celgene's method of treatment patents for myelodysplastic syndromes. As a result, Dr. Reddy's had a clear path to market by using what is referred to as a "skinny label"—a label that omits other indications to avoid patent infringement claims. Celgene's '740, '717, and '120 patents were anticipated by invalidating prior art, including press releases from years earlier. Dr. Reddy's introduced two press releases bearing dates that would have invalidated the patent. In response, Celgene *did not deny* that the press releases were in fact published on the relevant dates, but instead disingenuously argued that the dates on the press release did not *themselves* establish that the press releases were published. While the PTAB denied invalidation on this technicality, Dr. Reddy's—and Celgene—knew that Dr. Reddy's could easily remedy this evidentiary technicality during District Court proceedings and invalidate Celgene's method of use patents.

[69] ECF No. 67, at 4-5 (D.N.J. Dec. 22, 2017).

179. On September 17, 2020, Celgene and BMS announced a settlement of the litigation with Dr. Reddy's.[70] Similar to Celgene's agreement with Natco, Celgene's announcement provided only minimal details of the deal between Celgene and Dr. Reddy's. As stated in their press release:

> Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the U.S. beginning some time after the March 2022 volume-limited license date that Celgene previously provided to Natco. The specific volume-limited license date and percentages agreed-upon with DRL were not disclosed and are confidential. In addition, Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the U.S. beginning no earlier than January 31, 2026.

180. The settlement agreement between Dr. Reddy's and Celgene was consistent with the MFE included in the settlement with Natco and its marketing partners. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Dr. Reddy's. The volume-limited caps ensure that Dr. Reddy's has no incentive to compete on price (because, like Natco, it cannot benefit from any increased sales resulting from a price reduction).[71] As in the case of the settlement with Natco, Celgene also has no incentive to launch an AG. The net result of the agreement is to limit price competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices. The agreement with Dr. Reddy's solidified, and was in part induced by, Celgene's earlier agreement with Natco.

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[70] Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for Revlimid (lenalidomide) with Dr. Reddy's, *Available at,* https://www.businesswire.com/news/home/20200917005211/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-With-Dr.-Reddy%E2%80%99s.

[71] While Dr. Reddy's qualified for first-filer statutory exclusivity for two of the six formulations – the 2.5mg and 20mg capsules – neither Dr. Reddy's nor Natco have an incentive to compete on price.

181. As part of its unlawful anticompetitive strategy, Celgene filed two serial patent infringement suits against Lotus and Alvogen, Inc. (collectively, "Lotus"). It brought the actions only to delay generic entry into the lenalidomide market. But for Celgene's anticompetitive scheme, Lotus would have gained temporary and final approval far earlier and would have launched a competing product earlier than it actually did.

182. On September 6, 2017, Celgene filed a patent infringement action against Lotus for filing ANDA No. 210480 for various dosages of its generic Revlimid, which Celgene alleged would infringe its '517 Patent, '720 Patent, '977 Patent, '784 Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent.[72]

183. On July 10, 2018, Celgene filed another patent infringement action against Lotus, alleging Lotus's ANDA would also infringe its '357 Patent, '219 Patent, and the '598 Patent.[73] However, Celgene did not submit any of the patents in this case to the Orange Book as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. Celgene was required to identify any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its drug in its NDA or list any new patents obtained after submission of the NDA within thirty days,. Its lawsuit on patents that it failed to list in the Orange Book indicates that Celgene either filed a frivolous infringement claim for a patent that it did not believe could be reasonably asserted or failed to list patents properly, which could give rise to administrative action or potential additional antitrust liability if done to delay filing and further extend its monopoly.

[72] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842 (D.N.J.).

[73] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al*, No. 2:18-cv-11518 (D.N.J.).

184. Lotus filed answers and counterclaims in all actions, alleging that all of Celgene's asserted patents were invalid, unenforceable, or uninfringed.

185. On August 8, 2018, Celgene filed a Statement informing the court of its covenant not to sue Lotus for infringement of the '217 Patent.[74]

186. On December 17, 2018, the parties submitted a Joint Claim Construction Statement. Lotus argued that the method-of-use patents for multiple myeloma (the '498 patent, '095 patent, '621 patent, and '622 patent) were invalid for, amongst other reasons, indefiniteness of key terms which the parties agreed to address through expert discovery.

187. Invalidation and/or a favorable construction regarding these method-of-use patents, which expire on May 23, 2023, would have paved the way for Lotus and/or other generic rivals to launch a "skinny-label" generic Revlimid only labeled to treat multiple myeloma, thereby endangering Celgene's monopoly.

188. On February 22, 2019, Celgene and Lotus stipulated to bifurcating and staying all proceedings related to the REMS patents (the '720, '977, '784, '886, and '531 Patents), pending Celgene's appeal to the Federal Circuit of the PTAB's invalidation of the '720 Patent (ultimately affirmed on July 30, 2019).

189. On March 29, 2019, Celgene and Lotus announced a settlement of the patent lawsuits. The terms of the agreement are confidential, but Celgene and Lotus announced some details in a press release that is largely identical to that announcing the Dr. Reddy's settlement,[75] indicating a similar settlement with another Later-Filing Generic protecting sales at monopoly pricing.

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[74] Statement, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 81 (D.N.J. Aug. 8, 2018).

[75] https://www.businesswire.com/news/home/20190329005384/en/Celgene-Settles-U.S.-REVLIMID%C2%AE-Patent-Litigation-with-Alvogen.

190. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Lotus. The small volume-limited caps ensure that Lotus has no incentive to compete on price (because, like Natco, it cannot benefit from any increased sales resulting from a price reduction). As in the cases of the Natco and Dr. Reddy's settlements, Celgene has no incentive to launch an AG. The net result of the agreement is to limit price competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices. The agreement with Lotus solidified, and was in part induced by, Celgene's agreements with Natco and Dr. Reddy's.

191. As part of its unlawful anticompetitive strategy, Celgene filed four serial patent infringement suits against Cipla. It brought the actions to delay generic lenalidomide. Cipla's ANDAs are "skinny labels" that seek only to treat multiple myeloma and myelodysplastic syndromes.

192. On August 15, 2017, Celgene filed a patent infringement action against Cipla, for filing ANDA No. 210435 for various dosages of its generic Revlimid, which Celgene alleged would infringe the '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and the '622 Patent.[76] On May 8, 2018, Celgene filed another patent infringement action against Cipla, alleging Cipla's ANDA would also infringe the '357 Patent, '219 Patent, and the '598 Patent, none of which Celgene listed in the Orange Book as covering Revlimid.[77] On March 29, 2019, Cipla submitted a second ANDA, No. 213165. On July 3, 2019, Celgene filed another patent infringement action against Cipla, alleging Cipla's second ANDA would infringe the '800 Patent, the '217 Patent, the '569 Patent, the '498 Patent, the '095 Patent, the '621 Patent, the '622 Patent, the '740 Patent, the '717 Patent, and the '120 Patent.[78] On May 12, 2020, Cipla

[76] *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163 (D.N.J.).

[77] *Celgene Corp. v. Cipla Ltd.*, No. 2:18-cv-08964 (D.N.J.).

[78] *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J.).

submitted a third ANDA, No. 214618. On June 24, 2020, Celgene filed another patent infringement action against Cipla, alleging Cipla's third ANDA would infringe the '800 Patent, the '217 Patent, the '569 Patent, the '498 Patent, the '095 Patent, the '621 Patent, the '622 Patent, the '740 Patent, the '717 Patent, and the '120 Patent.[79]

193. Cipla filed answers and counterclaims in all actions, alleging that all of Celgene's asserted patents were invalid, unenforceable, or uninfringed.

194. On January 14, 2019, the court ordered mediation between the parties. On February 6, 2019, the parties informed the court that *Markman* hearings were no longer necessary.

195. On April 30, 2019, the court issued a stipulated order in which Cipla agreed not to contest that products derived from its ANDA would infringe Celgene's '357, '219, and '598 patents, none of which Celgene listed in the Orange Book as covering Revlimid, while Cipla reserved its rights to argue invalidity.

196. On May 28, 2020, Celgene filed its First Amended Complaint, alleging patent infringement arising from both of Cipla's ANDAs.[80] That day, the parties submitted a Joint Claim Construction Statement, informing the court of the absence of disputed terms. On June 8, 2020, Civil Action Nos. 18-08964 and 17-06163 were administratively terminated and incorporated by reference into Civil Action No. 19-14731.

197. On June 22, 2020, the court granted Cipla leave to serve amended noninfringement contentions regarding Celgene's method of use patents for multiple myeloma.[81]

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[79] *Celgene Corp. v. Cipla Ltd.*, No. 2:20-cv-07759 (D.N.J.).

[80] First Amended Complaint, *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731, ECF No. 64 (D.N.J.).

[81] Stipulation and Order, No. 2:19-cv-14731, ECF No. 67 (D.N.J. June 22, 2020).

On July 13, Celgene stipulated to a dismissal of its claims regarding the '217 Patent and filed a covenant not to sue Cipla for infringement of the '217 Patent.[82]

198. On August 21, 2020, Cipla moved for an order compelling Celgene's production of discovery. Celgene's opposition was due September 15. A telephone conference was set for November 23, 2020.

199. On December 11, 2020, Celgene announced a settlement agreement with Cipla.[83] The terms of the agreement are confidential, but Celgene and Cipla announced some details in a press release that is largely identical to those announcing the Dr. Reddy's and Lotus settlements,[84] indicating a similar settlement with another Later-Filing Generic designed to protect Celgene's monopoly.

200. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Cipla. The volume-limited nature of the license ensures that Cipla has no incentive to compete on price (because, like Natco, it cannot benefit from any increased sales resulting from a price reduction). As in the Natco, Dr. Reddy's, and Lotus cases, Celgene has no incentive to launch an AG. The net result of the agreement is to limit price competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices. The agreement with Cipla solidified, and was in part induced by, Celgene's agreements with Natco, Dr. Reddy's, and Lotus.

201. As part of its unlawful anticompetitive strategy, Celgene filed three serial patent infringement suits against Sun. It brought these actions only to delay generic lenalidomide.

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[82] Stipulation and Order of Dismissal, *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731, ECF No. 74 (D.N.J. Jul. 13, 2020).

[83] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Cipla.

[84] https://www.businesswire.com/news/home/20201211005052/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-with-Cipla.

202. In 2018, Sun filed ANDA No. 211846 for generic lenalidomide. Sun's ANDA is a "skinny label" seeking only to treat multiple myeloma. On May 30, 2018, Sun sent written notice of its Paragraph IV certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Sun's ANDA.

203. On July 13, 2018, Celgene filed a patent infringement action against Sun and related entities for filing its ANDA for various dosages of its generic Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, and '569 Patent.[85] On April 16, 2019, Celgene filed another patent infringement action against Sun, alleging that Sun's ANDA would infringe its '357 Patent, '219 Patent, and its '598 Patent, none of which Celgene listed in the Orange Book as covering Revlimid.[86] On February 2, 2021, Celgene filed another patent infringement action against Sun, alleging that Sun's ANDA would infringe its '498 Patent, '095 Patent, '621 Patent, and its '622 Patent.[87]

204. Sun filed answers and counterclaims in the first two actions (the third settled before Sun filed an Answer), alleging that all Celgene's asserted patents were invalid, unenforceable, or uninfringed.

205. On January 22, 2019, Celgene filed a Statement informing the court of its covenant not to sue Sun for infringement of the '217 Patent.[88]

206. On December 12, 2019, the court cancelled *Markman* hearings upon the parties' joint motion.

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[85] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:18-cv-11630 (D.N.J.).

[86] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:19-cv-10099 (D.N.J.).

[87] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:21-cv-01734 (D.N.J.).

[88] Statement, *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:18-cv-11630, ECF No. 50 (D.N.J. Jan. 22, 2019).

207. On June 21, 2021, Sun announced its settlement with Celgene.[89] The only details made available were that "Celgene will grant Sun Pharma a license to Celgene's patents required to manufacture and sell (subject to USFDA approval) certain limited quantity of generic lenalidomide capsules in the US beginning on a confidential date that is sometime after March 2022. In addition, the license will also allow Sun Pharma to manufacture and sell an unlimited quantity of generic lenalidomide capsules in the US beginning January 31, 2026."[90] The terms of the agreement are confidential, but Celgene and Sun announced some details in a press release that is largely identical to those announcing the Dr. Reddy's, Lotus, and Cipla settlements, indicating a similar settlement to another Later-Filing Generic.[91] As in the cases of the Natco, Dr. Reddy's, and Lotus settlements, Celgene has no incentive to launch an AG. The net result of the agreement is to limit price competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices. The agreement with Sun also solidified, and was in part induced by, Celgene's earlier agreements with Natco, Dr. Reddy, Lotus, and Cipla.

208. Celgene and BMS subsequently sued, and then settled with, Zydus and Apotex on terms similar to those contained in the earlier agreements with Natco, Dr. Reddy, Lotus and Cipla.

H. The Size of the Reverse Payment to Natco and Teva

209. The Celgene/BMS/Natco/Teva agreement was both an illegal horizontal output-restriction and market-allocation agreement and an anticompetitive reverse-payment agreement of the kind condemned by the Supreme Court in *Actavis*. The reverse payment took the form of

[89] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Sun.

[90] https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf.

[91] https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf.

volume-limited royalty-free licenses that began in March 2022 and most-favored-entry ("MFE") clauses that guaranteed Natco and Teva a limited share of the Revlimid market at prices close to the price of branded Revlimid.

210. A seller with a volume limit has no incentive to compete on price. Adding additional generic sellers with volume limits below the total demand for the generic will put no downward pressure on price.

211. Natco described the existence of the volume limits, but not their precise value, in its original press release announcing the settlement with Celgene. Additionally, during Natco's February 12, 2016 earnings call (held shortly after the Natco Revlimid settlement was announced), Natco CEO Rajeev Nannapaneni stated with respect to the Revlimid settlement agreement: "We have a launch date. The launch date is clear. It allows us to launch without paying a license fee[;] that is the arrangement that we have."[92]

212. The volume-limited, royalty-free license is essentially a side deal whereby the brand pays the generic by allowing it to make a limited volume of sales at a generic price very close to the branded price, regardless of the number of generics in the market. In this case, Natco and Celgene agreed that Natco would be allowed to capture 7% of the multi-billion-dollar Revlimid market at prices close to the price of branded Revlimid.

213. Celgene also agreed to provide volume-limited licenses to at least four of the Later-Filing Generics to start "sometime after March 2022" and likely limited to a "low-single digit percentage" of the market.[93] Celgene has continued to conceal the terms of these

[92] Natco Feb. 12, 2016 earnings call transcript at p. 20, available at https://natcopharma.co.in/wp-content/uploads/2016/02/NirmalBang-NatcoPharma-Feb12-2016.pdf (last accessed March 2, 2022).

[93] *See* https://www.businesswire.com/news/home/20200917005211/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-With-Dr.-Reddy%E2%80%99s; https://www.businesswire.com/news/home/20190329005384/en/Celgene-Settles-U.S.-REVLIMID%C2%AE-Patent-Litigation-with-Alvogen; https://www.businesswire.com/news/home/20201211005052/en/Bristol-Myers-

settlements. However, the settlements with the four Later-Filing Generics are *at least* complementary agreements that contain terms that are consistent with and carried out the expectations of the parties to the initial reverse-payment agreement with Natco.

214. In addition, Celgene made a payment to Natco in the form of a most-favored entry clause that disincentivized later-filing generics from continuing to challenge the Revlimid patents and ultimately resulted in settlements that included volume-limited licenses like the one agreed to by Natco. Had a later (non-settling) generic continued the litigation and succeeded in invalidating the patents, it would have triggered the most-favored entry clause, allowing at least Natco to enter the market early, cutting into the non-settling generic's market share and causing further price erosion. In other words, the challenger would bear 100% of the cost and risk associated with continuing the patent challenge but would enjoy only a fraction of the rewards if it were to succeed. As a result, most-favored entry clauses deter patent challenges and represent payments to the settling generic in the form of an assurance that it will receive the most-favorable entry date.

215. Natco has disclosed that the Revlimid settlement agreement contains an MFE, which, if triggered, would permit Natco to enter the market earlier than it otherwise would be allowed under the terms of the settlement agreement. One of the events that can trigger the most-favored entry clause is if another generic manufacturer pursues the patent litigation and succeeds in invalidating Celgene's patents. Without the clause, Natco would forfeit its lucrative 180-day exclusivity period if it could not launch within 75 days of the legal decision. The MFE clause permits Natco to launch quickly and retain its exclusivity, thus eliminating the risk that

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Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-with-Cipla; https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf.

Natco could lose its 180-day exclusivity period. The elimination of the risk of losing the exclusivity period was extremely valuable to Natco.

216. The size of the payment from Celgene and BMS to Natco and Teva can be approximated. Under competitive conditions, there are typically three versions of a branded pharmaceutical available during the 180-day generic exclusivity period: the brand product itself, the first-to-file generic's product, and the brand's authorized generic or AG. The two generic products quickly capture most of the market. The generics compete on price, bringing the price of the generic products down to no more than 40% of the brand price. After the exclusivity period expires, additional generics enter the market and drive the price of the generics down further, sometimes to as little as 10% of the brand price.

217. A no-AG clause is an anticompetitive promise from the brand not to compete with the generic during the 180-day exclusivity period, made in exchange for a delay in generic entry. According to the FDA, a generic product in a market with only one generic seller is priced at 61.4% of the brand price.[94] While no-AG agreements injure purchasers by maintaining higher generic prices after generic entry, they have virtually no effect on generic penetration and thus allow purchasers to achieve modest savings on nearly all of their purchases of the relevant drug at the time of generic entry. And since no-AG agreements typically last only six months, they permit full-fledged (albeit belated) generic competition six months after initial generic entry.

218. No-AG clauses are more anticompetitive than cash payments because they create a generic monopoly, rather than a generic duopoly, during the first six months after generic

[94] R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA: Generic Competition and Drug Prices (December 2019), available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last accessed March 29, 2022).

entry. In effect, no-AG clauses force purchasers to pay a portion of the compensation to the generic in the form of higher generic prices.

219. With a volume-limited license, the brand can retain the entire share of the market not allocated to the generic, so there is no incentive to launch an authorized generic. The sales volume of the volume-restricted generic is also fixed so it has no incentive to reduce its price to increase its sales volume. A volume-limited generic entrant that faces no additional generic competition will price its product very close to the brand price, as Teva did here.

220. In 2015, when the settlement occurred, a reasonable estimate was that monthly Revlimid sales would be approximately $540 million in March of 2022. Under normal competitive conditions, Celgene would be expected to launch an AG, and the two generic products (Natco's and the AG) would be expected to capture 70% of the total market from the brand. Assuming an equal split, Natco would capture 35% of the molecule's sales. Using a generic price equal to 61.4% of the brand price (see paragraph 217 above) and a 70% gross profit margin, Natco would earn profits of approximately $81 million during each month of its 180-day exclusivity period, or approximately $486 million during the full 180-day exclusivity period. Upon expiration of the exclusivity period, additional competitors would enter, Natco's share of the market would decline, the generic discount would increase, and Natco's expected profits would consequently decline.

221. Upon the expiration of exclusivity, assuming normal competitive conditions, it is reasonable to expect that Natco would obtain approximately a 20% share of the Revlimid market at a price equal to 20% of the branded price. Using the same monthly sales figure and gross profit margin used above, Natco would then expect to earn approximately $15 million per month during the second six months after launch, or $90 million dollars during that six-month period. Thus, under competitive conditions, Natco's anticipated profit during the first year after launch

would be approximately $576 million. Natco's profit would then remain steady at $180 million per year.

222. A similar approach may be used to estimate Natco's profits as a result of the volume-limited license/MFE agreement. While Natco's share of the market is capped at 7% during the first year after launch, the higher generic price more than offsets the restricted market share. Under the actual agreement, Natco was guaranteed 7% of the Revlimid market for a full year at a price very close to of the branded price (say 90%). Thus, Natco could expect to earn approximately $24 million per month starting in March 2022, or $288 million from March 2022 through February 2023. Unlike the calculation assuming competitive conditions, Natco's expected profit goes *up* over time, not down. If we assume that Natco's share rises from 7% to 14% in the second year (March 2023 through February 2024), Natco would earn $576 million during that period. If we assume another 7-point increase to 21% during the following year (March 2024 through February 2025), and a limit of 33 1/3% from March 2025 to January 2026, Natco's expected profit from March 2024 to January 2026 totals $1.99 billion ($864 million + $1,134 million), for a total expected profit of approximately $2.86 billion prior to January 31, 2026.

223. By contrast, Natco's expected profit under competitive conditions is $576 million during the first year (March 2022 through February 2023); $180 million during the second year (March 2023 through February 2024); $180 million during the third year (March 2024 through February 2025); and $150 million during the final ten months (March 2025 through January 2026), for a total expected profit of $1.09 billion.

224. These figures are shown in tabular form below. As noted in the table, the present value (as of 2015) of the difference between Natco's expected profits under competitive conditions and its expected profits under the volume-limited/MFE agreement with Celgene

equals $706.3 million using a 10% discount rate. That is a reasonable estimate of the size of the payment from Celgene and BMS to Natco and Teva.

Time Period	Competitive Conditions	Volume-limited License	Delta	PV as of 2015 @ 10%
3/22-2/23	$576 million	$288 million	($288 million)	($147.8 million)
3/23-2/24	$180 million	$576 million	$396 million	$184.7 million
3/25-2/25	$180 million	$864 million	$684 million	$290.1 million
3/25-1/26	$150 million	$1.134 billion	$984 million	$379.3 million
TOTAL	$1.09 billion	$2.86 billion	$1.77 billion	$706.3 million

225. These calculations do not include an estimate of growth in the Revlimid market after March 2022, but incorporating such an estimate would only increase the size of the payment.

226. In addition to the enormous value given to Natco and Teva in the reverse-payment agreement, the reverse payment represented an economic sacrifice to Celgene and BMS at least equal to the profits they would have earned by launching an AG under normal competitive conditions (approximately equal to what Natco would have expected to earn under competitive conditions). Of course, the profits Celgene and BMS earned by delaying generic competition until 2026 far outweighed that sacrifice.

I. Anticompetitive Impact of the Reverse Payment

227. As noted above, a reverse payment in the form of a no-AG agreement is worse than a cash payment because it delays generic entry *and* maintains higher generic prices after generic entry, typically for six months, while a cash payment simply delays generic entry. The volume-limited license agreements that Celgene entered into with Natco and the Later-Filing Generics are even more anticompetitive than a no-AG agreement in two respects. First, since a seller with a volume limit has no incentive to lower prices, these agreements ensured that generic Revlimid would be priced very close to the brand price from March 2022 through January 2026. Second, the volume-limited license agreements have artificially capped and will continue to

artificially cap the generic market share at much lower levels than would be expected under normal competitive conditions. By contrast, a no-AG agreement has virtually no effect on generic penetration, and its effect on generic prices typically lasts only six months. In other words, a no-AG clause keeps the generic price artificially high for six months, while the Revlimid market-division scheme will keep generic prices substantially higher, and generic substitution artificially lower, for almost four years.

228. Celgene continued to file patent infringement litigation against any generic Revlimid ANDA filer. Celgene and the Later-Filing Generics have kept *all* the terms of their settlement agreements confidential.

229. Celgene and BMS's scheme was intended to and did in fact block and delay generic lenalidomide entry into the market. It destroyed incentives for price competition, disrupted the normal distribution channels, and manipulated the statutory and regulatory mechanisms by which generic competition takes place, and otherwise excluded generic competitors from competitively marketing and distributing their products.

230. The Revlimid reverse payment, output-restriction and market-allocation agreement will prevent true generic competition for Revlimid until at least January 31, 2026. As a result, Plaintiffs have been and will continue to be forced to purchase brand Revlimid at supra-competitive prices through at least early 2026. Plaintiffs have also paid and will continue to pay supracompetitive prices for generic Revlimid until at least January 31, 2026.

231. Absent Defendants' unlawful conspiracy, generic Revlimid would have been available no later than 2019.

232. Such entry would have occurred because, absent the unlawful payment, a reasonable generic company in the position of Natco/Teva would have: (i) launched generic Revlimid after prevailing at trial, (ii) launched at risk, or (iii) entered into a payment-free

agreement that provided for an earlier agreed entry date. Celgene would have launched an AG simultaneously with the launch of the first generic and additional generic competitors would have launched six months later. Plaintiffs would have substituted lower-priced generic Revlimid for higher-priced branded Revlimid at the time of generic entry, and would have paid lower prices for the generic Revlimid they were belatedly permitted to purchase, in limited volumes, starting in March 2022.

233. Absent Defendants' unlawful conduct, Plaintiffs would have paid less for lenalidomide by substituting purchases of less expensive AB-rated generic Revlimid for purchases of more expensive branded Revlimid, by paying lower prices for the limited volume of generic Revlimid they have been allowed to purchase since March 2022, and by purchasing generic versions of Revlimid at lower prices sooner.

234. As a result, Plaintiffs have sustained substantial loss and injury to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VI. INTERSTATE COMMERCE

235. Revlimid is sold in interstate commerce, and the unlawful activities alleged herein have substantially affected interstate commerce.

VII. MARKET POWER AND MARKET DEFINITION

236. At all relevant times, Celgene has had monopoly power over the market for Revlimid in all its forms and dosages, even after the launch of generic Revlimid in March 2022. Celgene has and continues to have the power to maintain and increase the price of Revlimid to supracompetitive levels without losing sales.

237. A small, but significant, non-transitory price increase on Revlimid by Celgene would not have caused a significant loss of sales.

238. Celgene needed to control only Revlimid and its AB-rated generic equivalents, and no other products, to maintain the price of Revlimid at supracompetitive prices. As stated above, Celgene's executives understood that Celgene had this power. They believed that they could raise the price of Revlimid "any time they wanted." Only the unrestricted market entry of a competing AB-rated generic version of those drugs would render Celgene unable to maintain its market monopoly.

239. The relevant product market consists of all strengths of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents.

240. Revlimid does not exhibit significant, positive cross-elasticity of demand regarding price with any other product, due to FDA regulatory hurdles incident to securing an AB rating and laws allowing pharmacists to substitute only AB-rated generics for prescribed branded drugs.

241. There are no interchangeable drug products available for purchasers of Revlimid.

242. Other drugs that are not AB-rated to Revlimid cannot be substituted automatically for Revlimid by pharmacists, do not exhibit substantial cross-price elasticity of demand with Revlimid, and thus are not economic substitutes for, nor reasonably interchangeable with, Revlimid.

243. The existence of other products designed to treat the conditions treated by Revlimid have not constrained Celgene's and BMS's pricing of Revlimid to the competitive level. Celgene and BMS have never lowered the price of Revlimid in response to the pricing of other branded or generic drugs.

244. Celgene and BMS needed to control only the sales of Revlimid and its generic equivalents, and no other products, in order to maintain the price of Revlimid profitably at supracompetitive prices. Only the unrestrained market entry of an AB-rated generic version of

Revlimid would render Celgene and BMS unable to profitably maintain prices of Revlimid at current levels without losing substantial sales.

245. Celgene's and BMS's reverse payment to Natco and Teva demonstrate that Celgene and BMS enjoyed monopoly power in the relevant market.

246. Celgene also sold branded Revlimid at prices well above marginal costs, and substantially more than the competitive price, and enjoyed unusually high profit margins.

247. Celgene has had, and so exercised, the power to exclude and restrict competition for Revlimid.

248. Without the power to exclude and restrict competition for Revlimid, and the ability to sell its own branded version of those drugs at prices well over marginal costs, it would not have been economically rational for Celgene to make exorbitant payments to settle with Natco to delay the launch of generic Revlimid.

249. At all relevant times, Celgene has enjoyed the benefits of high barriers to entry with respect to competition in the above-defined market due to patent and other regulatory protections.

250. At all times before March 2022, Celgene and BMS possessed a 100% share of the relevant market, indicating substantial monopoly power. They continue to possess an overwhelming share of the relevant market today.

251. The relevant geographic market is the United States and its territories.

VIII. ANTITRUST INJURY

252. Defendants' unlawful conduct injured Plaintiffs by forcing them to pay higher prices for their requirements of branded and generic lenalidomide than they would have paid in the absence of that conduct.

253. Plaintiffs paid substantial sums to purchase Revlimid directly from Celgene and BMS during the relevant time period at prices substantially higher than the prices Plaintiffs would have paid for the drug in the absence of the illegal conduct. Plaintiffs continue to pay artificially high, supracompetitive prices for Revlimid as a direct and proximate result of Defendants' anticompetitive conduct. Plaintiffs have also paid overcharges on their purchases of generic Revlimid directly from Teva since March 2022.

254. Prices for Revlimid and generic Revlimid have been and will continue to be inflated as a direct and foreseeable result of Defendants' anticompetitive conduct. Defendants' unlawful conduct will continue to force Plaintiffs and other purchasers to pay higher prices for the drug until at least January 2026.

255. The overcharges that Plaintiffs have paid and will continue to pay are injury of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

IX. CLAIMS FOR RELIEF

CLAIM ONE
CONSPIRACY IN RESTRAINT OF TRADE (ALL DEFENDANTS)

256. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 255 above. This claim is asserted against all Defendants.

257. Beginning in 2015, and continuing through the present day, Defendants have entered into a continuing unlawful contract, combination and conspiracy in violation of section 1 of the Sherman Act, 15 U.S.C. § 1. Specifically, Celgene, BMS, Natco and Teva entered into an unlawful horizontal agreement to restrict output and allocate the Revlimid market beginning in March 2022, thereby transferring billions of dollars in value to Natco and later Teva in return for Natco's agreement to delay the launch of its AB-rated generic Revlimid until March 1, 2022.

258. Defendants' settlement agreement constitutes a horizontal output-restriction and market-allocation agreement—a *per se* violation of the Sherman Act.

259. In the alternative, Defendants' unlawful agreement substantially harmed competition in the relevant market by delaying the availability of less expensive generic Revlimid, artificially maintaining the price of Revlimid at supracompetitive levels and artificially maintaining the price of generic Revlimid at supracompetitive levels.

260. Defendants' unlawful conspiracy (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide from at least 2019 until March 2022; (b) delayed the availability of generic lenalidomide from at least 2019 until March 2022; (c) allocated 7% of the Revlimid market to Natco and Teva from March 2022 until February 2023; (d) allocated unknown percentages of the Revlimid market to Natco and Teva from February 2023 through January 31, 2026; (e) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (f) ensured that generic prices would remain artificially high, and generic substitution artificially low, from March 2022 until January 20, 2026; and (g) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

261. As a result of Defendants' unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

262. There was and is no legitimate, non-pretextual, pro-competitive justification for this reverse payment agreement that outweighs its harmful effect on competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose.

263. The anticompetitive effects of Defendants' reverse-payment agreement agreements continue to this day and will continue through at least January 2026.

264. As a direct result of Defendants' unlawful conspiracy, Plaintiffs have suffered and will continue to suffer injury to their business and property in the form of overcharges.

CLAIM TWO
MONOPOLIZATION (CELGENE AND BMS)

265. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 255 above. This claim is asserted against Defendants Celgene and BMS.

266. At all relevant times, Celgene and BMS have enjoyed monopoly power in the relevant market. That monopoly power will continue to exist until at least January 31, 2026.

267. Celgene and BMS have knowingly and willfully maintained their monopoly power in the relevant market by a course of conduct that has prevented generic manufacturers from launching AB-rated generic versions of Revlimid and by colluding with actual or potential generic competitors to suppress and delay generic competition. This course of conduct has included: (a) refusing to sell or otherwise provide samples of Revlimid to generic manufacturers; (b) fraudulently procuring patents; (c) abusing the REMS process; (d) abusing the Citizen Petition process; (e) improperly and serially filing and prosecuting patent infringement actions against generic manufacturers without regard to their merit or likely outcome; and (f) entering into the reverse payment/horizontal output-restriction and market-allocation agreements described above. Celgene's and BMS's conduct amounts to unlawful monopolization proscribed by section 2 of the Sherman Act, 15 U.S.C. § 2.

268. Celgene and BMS have maintained their monopoly power by colluding with and excluding competitors, and not from growth or development resulting from a superior product, business acumen, or historic accident.

269. Celgene's and BMS's unlawful monopolization (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide from at least 2019 until March 2022; (b) delayed the availability of generic lenalidomide from at least 2019 until March 2022; (c) allocated 7% of the

Revlimid market to Natco and Teva from March 2022 until February 2023; (d) allocated unknown percentages of the Revlimid market to Natco and Teva from February 2023 through January 31, 2026; (e) allocated unknown percentages of the Revlimid market to certain Later-Filing Generics beginning some time after March 2022 and continuing until January 31, 2026; (f) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (g) ensured that generic prices would remain artificially high, and generic substitution artificially low, from March 2022 until January 20, 2026; and (h) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026. (c) ensured that generic prices would remain artificially high, and generic substitution artificially low, from March 2022 until January 20, 2026; and (d) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

270. The goal, purpose and effect of the conduct alleged herein was to maintain, enhance, and extend Celgene's and BMS's monopoly power, in violation of Sherman Act Section 2, 15 U.S.C. § 2.

271. Defendants Celgene and BMS knowingly and intentionally maintained, enhanced, and extended their monopoly power in the relevant market.

272. As a result of Celgene's and BMS's unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

273. The anticompetitive effects of Celgene's and BMS's unlawful monopolization continue to this day and will continue through at least January 2026.

274. As a direct result of Celgene's and BMS' unlawful monopolization, Plaintiffs have suffered and will continue to suffer injury to their business and property in the form of overcharges.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged above is in violation of sections 1 and 2 of the Sherman Act;

B. Permanent injunctive relief enjoining Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to dissipate the continuing effects of that unlawful conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled as provided by law;

D. An award of Plaintiffs' costs and reasonable attorneys' fees; and

E. Such other and further relief as the Court may deem just and proper.

XIII. JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: November 3, 2022

Respectfully submitted,

/s/ *Deborah S. Corbishley*

Deborah S. Corbishley
KENNY NACHWALTER P.A.
Four Seasons Tower, Suite 1100
1441 Brickell Avenue
Miami, FL 33131
Telephone: (305) 373-1000
Facsimile: (305) 372-1861
Attorneys for Plaintiffs

Of counsel:

Scott E. Perwin
Lauren C. Ravkind
Anna T. Neill
KENNY NACHWALTER P.A.
Four Seasons Tower, Suite 1100
1441 Brickell Avenue
Miami, FL 33131
Telephone: (305) 373-1000
Facsimile: (305) 372-1861
Email: sep@knpa.com
Email: lcr@knpa.com
Email: atn@knpa.com